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PHARMACEUTICAL INDICATORS:

**A METHODOLOGY FOR RAPIDLY ASSESSING
KEY ASPECTS OF DRUG SYSTEM PERFORMANCE**

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I.	INTRODUCTION	1
A.	Background	1
B.	Objectives of the Pharmaceutical Indicators Matrix	3
C.	Contents of this Manual	4
II.	OVERVIEW	5
A.	Categories of Indicators	5
III.	INDICATORS DESCRIPTION FORMAT	7
IV.	DESCRIPTION OF INDICATORS	8
A.	Policy, Legislation and Regulation	8
B.	Formulary/Essential Drugs List	13
C.	Public Sector Budget and Finance	18
D.	Public Sector Pharmaceutical Procurement	25
E.	Public Sector Pharmaceutical Logistics	29
F.	Drug Utilization and Patient Access	35
G.	Product Quality Assurance	40
H.	Private Sector Pharmaceutical Activity	43
V.	STUDY DESIGN	52
A.	Obtain a Representative Picture of the Entire System	52
B.	Enumerate Appropriate Number of Health Facilities	53
C.	Select Retail Pharmacies	54
D.	Select Tracer Drugs	54
E.	Select a List of Products Currently Available in Market	55
VI.	DATA COLLECTION	57
A.	Interviews with Health Officials	57
B.	Document and Record Review	57
C.	Physical Inventories of Drug Stock	57
D.	Surveys	58
VII.	PLANNING FIELDWORK AND TRAINING	62
A.	Select Study Areas and Facilities	62
B.	Identify MOH Officials	62
C.	Make Logistical Arrangements	63
D.	Recruit and Train Data Collectors	63
VIII.	REPORTING FINDINGS	65
A.	Reporting at the Administrative Level	65
B.	Reporting Results at the Facility	65

Table 1: List of Proposed Pharmaceutical System Indicators	6
Table 2: Form for Calculating Percentage of Time out of Stock for Tracer Drugs	33
Table 3: Selection of Smaller Samples of 20 Products from Larger List of Products in Market	56
Table 4: Potential Resources for Gathering Information on Indicators	60
Table 5: Model Training Course for Data Collectors	64
Annex 1: Suggested List of Tracer Drugs By Therapeutics Category	66
Annex 2: Examples of Data Collection Forms	67
Annex 3: References	73
Annex 4: Field Test Results	74

I. INTRODUCTION

This manual is the result of an ongoing effort to develop and test a matrix of process and outcome indicators, which can be used to monitor and compare significant aspects of pharmaceutical systems in developing countries, and to assist with project design and evaluation. The work has been done under the auspices of two projects financed by the U.S. Agency for International Development.

Initial development and field testing of the methodology was done by a working group led by the Management Sciences for Health Drug Management Program and the Harvard Drug Policy group, with support and guidance from the Latin America/Caribbean Health, Nutrition and Sustainability (LAC-HNS) Contract, which is managed by the University Research Corporation. Input into the first draft list of indicators was provided by the Ghana and Indonesia Core Groups of the International Network for Rational Drug Use (INRUD).

Additional field tests have been accomplished through country pharmaceutical sector assessments done by the USAID financed Rational Pharmaceutical Management Project (RPM), which is composed of USAID cooperative agreements with Management Sciences for Health and the United States Pharmacopeia. A summary of data from the field tests is provided in Annex 4.

A. Background

Pharmaceutical supply systems in developing countries have severe problems, including ineffective procedures in selection, poor quality control, and economically inefficient procurement. This has been documented in numerous reports.¹⁻⁴ Nonetheless, there is no standard method for measuring effectiveness of these systems. A formal framework based on reliable performance measures is needed for:

- Assessing strengths and weaknesses
- Comparing pharmaceutical systems
- Designing intervention projects
- Monitoring changes in systems and the impact of interventions

The LAC/HNS and RPM work builds on and complements other activities directed at developing indicators for pharmaceutical systems and sectors.

Indicators have been used for years in "developed" countries to measure aspects of pharmaceutical systems. Notable examples of pharmaceutical indicators use in the United States include the Bureau of Health Care Delivery (BCRR Indicators), the Joint Commission on Accreditation of Healthcare Organizations, and the recent efforts of the Quality Assurance Indicators Development Group of the American Society of Hospital Pharmacists. The focus of these sets of indicators is relatively specific to U.S. institutions.

The World Health Organization, and in particular the WHO Drug Action Programme, have recognized the need for formal indicators which would allow valid and consistent analysis of developing country pharmaceutical systems. In 1988, WHO published the World Drug Situation. That book compiled and presented an enormous amount of useful data, though the indicators which were presented in the book seemed to be more accurately defined in some cases as subjective ratings, which could and should be based on explicit indicators. In order to make these ratings objectively useful in comparing pharmaceutical systems in different countries, the indicators underlying the ratings would need to be identified.

In February of 1993, The WHO Action Programme on Essential Drugs issued a draft manual - *Indicators for Monitoring National Drug Policies in Developing Countries* - which proposes a set of 32 general data indicators, 48 structural indicators and 37 process indicators. These indicators are intended for self use by developing countries to monitor their pharmaceutical systems; the Drug Action Programme worked with a group including the Harvard School of Public Health and the Centre de Recherches et d'Etudes pour le Développement de la Santé (CREDES - Paris, France). It is uncertain to what extent these indicators have been applied.

The International Network for Rational Use of Drugs (INRUD) is a network promoting rational drug use, involving seven African and Asian countries which is coordinated by Management Sciences for Health (MSH) and the Harvard Drug Policy Group. Sponsors include WHO, DANIDA, USAID, SIDA, and the PEW Charitable Trusts.

INRUD has developed and field tested a set of indicators related to rational drug use, which is a major component of overall pharmaceutical management; the INRUD drug use indicators have been adopted by WHO as the standard methodology for assessing drug use, and published as the Action Programme on Essential Drugs manual *How to Investigate Drug Use in Health Facilities*.

The Pan-American Health Organization has sponsored an on-going project to develop and test indicators which could be used to measure progress of Essential Drugs Projects in Central America. The data from this work has been collated and assembled by the PAHO Regional Essential Drugs Advisor.

The intention of both the LAC-HNS Contract and the RPM Project is that the indicator matrix presented here will be harmonized with WHO and PAHO work. To that end, a meeting was held in October of 1993 involving LAC-HNS, MSH and RPM, and PAHO Essential Drugs Programme staff. The purpose of the meeting was to compare terminology, methodology and results of surveys, and to standardize terminology and methods to the extent feasible.

A similar meeting had been tentatively planned for late 1993 with the WHO-Drug Action Programme, but it has been postponed; the LAC-HNS and RPM objective for this meeting would be again to standardize methods and terms, so that the matrix of indicators described here becomes in effect a sub-set of the larger WHO indicator set.

B. Objectives of the Pharmaceutical Indicators Matrix

The goal of the LA/C and RPM indicator development process is to develop a matrix of indicators which could be used by developing country senior managers, international agencies, and donors to monitor pharmaceutical systems on a regular basis.

This means that the ultimate matrix should be as compact as possible, so that the data can be collected in a reasonable time frame and non-specialists could use the matrix effectively.

There are four general criteria for useful indicators:

- **Importance** - each indicator must reflect an important dimension of performance.
- **Measurability** - indicators must be measurable, within existing constraints of time and variable quality of source data.
- **Reliability** - each indicator should be reliable over time and with different observers.
- **Validity** - each indicator must allow a consistent and clear interpretation and have a similar meaning across health environments.

It is necessary to strike a balance between conflicting needs when assembling a research tool. On the one hand, it is scientifically important to assemble comprehensive data sets, to assure that interpretations and conclusions are maximally valid and reliable. On the other hand, more compact data sets are often mandatory in a management tool which is to be used regularly, in order to avoid data overload, and so that the costs of gathering and analyzing data are not prohibitive.

It is also important to recognize that, although the term "indicators" is used for convenience, the indicators proposed in this manual are not indicators in the truest sense, but rather are standardized measurements of the local pharmaceutical system. There is not enough data available yet to be able to make judgements as to norms for any of the measures, or to determine which of the measurements have sufficient diagnostic worth to be used as standard indicators. For example, we may be able to say that a country has a national formulary with 400 discrete drug products, but we are unable to say if this is too many or too few items for a national formulary list, or indeed whether a national formulary list is a necessary feature of a healthy public sector pharmaceutical system.

As more data is gathered using consistent methodology, it should become possible to determine to what extent these proposed standard measurements meet the criteria of **importance, measurability, reliability, and validity**, and to begin to establish normal ranges of performance for each of the indicators.

C. Contents of this Manual

This manual has seven chapters:

Chapter I Introduction

Chapter II (Overview) outlines the matrix of indicators and shows how information on each of the indicators is presented in this manual.

Chapter III Indicator Description Format

Chapter IV (Description of Indicators) defines each indicator, gives the purpose of its collection, and a summary of methodology of data collection, and of how to compute and present results.

Chapter V (Study Design) discusses methodological ways of making the results of the survey more reliable.

Chapter VI (Data Collection) discusses the four data collection strategies.

Chapter VII (Planning Fieldwork and Training) lists steps for carrying out the assessment of a pharmaceutical system.

Chapter VIII (Compiling and Reporting Indicator Data) offers suggestions concerning compiling indicator data and reporting the data to host country government officials.

II. OVERVIEW

A. *Categories of Indicators*

The eight conceptual categories of indicators aim to cover both policy and practice dimensions of a country's pharmaceutical system. The categories are:

POLICY, LEGISLATION AND REGULATION

FORMULARY/ESSENTIAL DRUGS LIST

PUBLIC SECTOR DRUG FINANCE

PUBLIC SECTOR PROCUREMENT

PHARMACEUTICAL LOGISTICS

DRUG UTILIZATION AND ACCESS

PRODUCT QUALITY ASSURANCE

PRIVATE SECTOR

The proposed indicators in each category are listed on the following page; when considering this list, it is important to remember that the objective is that indicators must meet the tests of importance, measurability, reliability and validity, and that a team of two consultants and local counterparts should be able to collect the entire data set within a one month period.

Table 1: List of Proposed Pharmaceutical System Indicators

<p>A. POLICY, LEGISLATION AND REGULATION</p> <ol style="list-style-type: none"> 1. Existence of a National Drug Policy approved by Government 2. Existence of comprehensive drug control legislation and regulations 3. Presence of unregistered drug products in a sample of private sector sales outlets 4. Information retrieval from drug registration information system 5. Law regarding generic substitution
<p>B. FORMULARY/ESSENTIAL DRUGS LIST</p> <ol style="list-style-type: none"> 1. Number of drugs on National Formulary List 2. Existence of a sub-set Essential Drugs List 3. Existence of a National Drug Formulary Manual providing basic drug information for prescribers, revised within the last five years. 4. Presence in public sector health facilities of an edition of the National Formulary Manual or Essential Drugs List Manual, revised within the last five years 5. Existence of a drug information center which is officially recognized by the Ministry of Health
<p>C. PUBLIC SECTOR BUDGET AND FINANCE</p> <ol style="list-style-type: none"> 1. Public sector budget or expenditures on pharmaceuticals, \$US per capita 2. Existence of a system for recovering costs of drugs dispensed in the public sector 3. Percentage of patients paying a charge for drugs in public sector health facilities 4. Percentage of total government recurrent budget used for Ministry of Health 5. Percentage of total MOH recurrent budget used for pharmaceuticals
<p>D. PUBLIC SECTOR PHARMACEUTICAL PROCUREMENT</p> <ol style="list-style-type: none"> 1. Existence of policy limiting public sector pharmaceutical procurement to the national formulary list 2. Coverage by a centralized system for routine procurement of public sector drugs 3. Percentage of average international price paid for last regular procurement (of a set of tracer drugs) 4. Percentage of MOH drugs centrally purchased through competitive tender
<p>E. PUBLIC SECTOR PHARMACEUTICAL LOGISTICS</p> <ol style="list-style-type: none"> 1. Percent of inventory variation in the stock record keeping system 2. Percent of stock records that correspond with physical count 3. Availability in public sector health facilities of a set of tracer drugs used to treat common diseases 4. Average percentage of time out of stock of a set of tracer drugs 5. Number and value of expired drug products in stock
<p>F. DRUG UTILIZATION AND PATIENT ACCESS</p> <ol style="list-style-type: none"> 1. Population per public health facility which dispenses drugs 2. Average number of drugs prescribed per curative encounter 3. Percentage of drugs prescribed by generic name 4. Percentage of patients receiving injections 5. Percentage of patients receiving antibiotics 6. Percentage of prescribed drugs which are dispensed
<p>G. PRODUCT QUALITY ASSURANCE</p> <ol style="list-style-type: none"> 1. Number of drug products tested by the Ministry of Health during the past year 2. Use of WHO Certification Scheme 3. Existence of a functioning system for reporting product quality complaints
<p>H. PRIVATE SECTOR PHARMACEUTICAL ACTIVITY</p> <ol style="list-style-type: none"> 1. Population per private sector drug sales outlet 2. Number of drug outlets per government drug inspector 3. Number of inspections made in one year period for manufacturers, distributors and retail outlets 4. Value of total private sector pharmaceutical sales, \$US per capita 5. Total value of drug market, public and private sector, \$US per capita 6. Percentage of products on National Formulary List currently manufactured in country 7. Prices of tracer drugs in the private sector 8. Existence of price controls for drugs 9. Availability of antibiotics without a prescription

III. INDICATORS DESCRIPTION FORMAT

Each indicator is described in the following format in the next chapter:

- Purpose:** The rationale for collecting the information.
- Definition:** The meaning of the terms used to describe this indicator.
- Data Collection Site:** The most likely source(s) of information.
- Data Collection Methodology:** By what processes are the data collected?
What types of data are involved?
What are necessary prerequisites and assumptions?
What happens if data are not available?
- Computation & Presentation:** Computations (if any) which are needed and suggested format for presenting the results.
- Example:** An example to demonstrate how the indicator might appear.
- Data to measure the indicators can be collected at three different levels of the health system (see Overview). Each indicator in the descriptions that follow is coded according to the level at which it is measured, with the code appearing after the indicator title. The level codes used are:
- C Central level
 - R Regional or district level
 - P Peripheral or facility level

IV. DESCRIPTION OF INDICATORS

A. *Policy, Legislation and Regulation*

A.1. Existence of a National Drug Policy Approved by Government (C)

Purpose: To determine whether an officially approved document exists which contains the components of a national drug policy recommended by the WHO.⁵

Definition: A national drug policy is an officially approved written document with guidelines pertaining to:

- Control of import, export, manufacture, and pricing of drugs, and of distribution, supply, storage and sale
- Authority for regulation of labeling, information and advertising, drug registration, scheduling of controlled substances, imposition of fees and price controls
- Drug control administration: organization and function, prescribing and dispensing restrictions, mechanisms of appeals against decisions

Data Collection

Site(s): MOH/Central Level Government Registry

Data Collection

Methodology: The National Drug Policy should be a written document issued at a single point in time as the basis for current official policy in the pharmaceutical sector. This document should be identified through interviews with key officials and a search of archived records. A copy should be made available to the assessment team and/or as a reference in the MOH.

Computation &

Presentation: Score the existence of a National Drug Policy according to the following categories:

- a. Present (with year approved or revised)
- b. Currently under development
- c. Absent

Example: In country A, the national drug policy is described in Política Nacional del Sector Salud (revised October, 1987).

A.2. Existence of comprehensive drug control legislation and regulations (C)

Purpose: To assess whether key aspects of comprehensive drug control legislation exist, and whether a central agency has been assigned responsibility for enforcing regulations in these areas.

Definition: Comprehensive drug control legislation is defined as written, officially approved legislation and regulation applying to: drug manufacturing, registration, distribution, prescribing, and sales practices, as well as regulations assigning official responsibility for enforcement of these rules.

Data Collection

Site(s): MOH, Drug Regulatory Authority, Ministry of Industry, or other relevant ministry

Data Collection

Methodology: Through document review and interviews with officials in the MOH, Drug Regulatory Authority, or other key agencies, determine if legislation exists in areas listed below, and which agency has been assigned responsibility for enforcing these regulations.

Computation &

Presentation: For each of the key aspects of a comprehensive drug legislation mentioned above, indicate whether or not legislation is in place, and whether an enforcing authority has been assigned.

Example: In country A, the existence of components of drug control legislation was as follows:

Legislative Area	Legislation in Place	Enforcing Agency in Place
drug manufacturing	YES, Food & Drug Act, 1989	YES, Pharmaceutical Supply Division, MOH (PSD/MOH)
drug registration	YES, Food & Drug Act, 1989	YES, PSD/MOH
drug distribution	YES, Food & Drug Act, 1989	YES, PSD/MOH
authorization to prescribe drugs	YES, Medicines Act, 1989	YES, National Medical Association
authorization to sell drugs	YES, Medicines Act, 1989	YES, National Pharmacy Council
drug marketing and promotion	Yes, Medicines Act, 1989	Yes, PSD/MOH

A.3. Presence of un-registered drug products in a sample of private sector sales outlets (C)

Purpose: To assess whether pharmaceutical products available on the market are officially registered, which is the basis of effective product control.

Definition: This indicator measures how completely regulations regarding drug registration have been implemented. A product is considered officially registered when the drug is listed on an official register of products approved for sales or distribution in the country. The indicator applies to all pharmaceutical products as identified in national legislation, both legend (prescription required) and non-legend; products classified as foodstuffs are excluded.
Note: If there is no law in effect requiring registration of drugs, this indicator is not relevant.

Data Collection site(s): Drug Regulatory Authority, MOH, or organization empowered with registration function.

Data Collection Methodology: Select a random sample of 10-20 retail drug sales outlets. At each site select from the shelves 10 products and record the complete names and product specifications. This gives a total of 100 products. If working with more than one enumerator, duplication can be avoided by assigning each enumerator a range of letters of the alphabet, with instructions to select products within the assigned range.

Computation & Presentation: Check the drug registration data base to see if any of the 100 product names collected are **not** registered. The indicator is specified as either *yes* (unregistered products were found in the sample) or *no* (all products in the sample were registered). Record the number of unregistered products, and compute the percentage of sample products which are not registered, as follows: Number of un-registered products, divided by the number of products sampled. Multiply by 100 to obtain percentage.

$$\% \text{ Un-registered Products} = \frac{\text{Number Un-registered Products}}{\text{Number Products}} \times 100$$

Example: In country A, 6 products out of a sample of 100 selected were found not to be registered.

A.4. Information retrieval from drug registration information system (C)

Purpose: To assess whether an operational drug registration information system exists, in the form of either a computerized or a manual database system.

Definition: A drug registration system should record pharmaceutical product information supplied at the time of registration, including the name of the company which registered the drug, when it was registered, and complete product description. An operational system should also contain a workable mechanism for retrieving information on registration status (computerized or not).

Note: If drug registration is not required by law, this indicator is not relevant.

Data Collection

Site(s): Drug Regulatory Authority, MOH, Ministry of Industry, or wherever the registration function is performed

Data Collection

Methodology: Observe whether registration officials can retrieve up-to-date information on the registration status of ten or more products, and how they do so. In order for the system to be considered functional, the records retrieved should contain at a minimum 1) Accurate name of current, registered drugs, with the ability to identify brand name (if any) and generic names; 2) Strength of all active ingredients and dosage form; 3) Name of company which registered the drug; 4) Name of manufacturer (if different); 5) Date product registered and period for which marketing is approved; and 6) Ability to list all registered products for a specific generic product.

Computation &

Presentation: Describe the registration information system according to the following criteria:

- a. The system is computerized or manual.
- b. Describe functionality of the system, what if any of the following information can be retrieved.

Example: In country A, a computerized drug registration system exists, but it appears to be only partially functional in that it could produce only three of the five types of information requested for a sample of 20 products.

A.5. Law regarding generic substitution by pharmacists (C)

- Purpose:** To determine whether it is legal for pharmacists to substitute generic drugs for prescribed proprietary drugs.
- Definition:** This indicator measures the existence of a written law or regulations exist that allows all qualified pharmacists, or ones practicing in certain settings, to substitute generic drugs for prescribed proprietary drugs, when the substituted drug is chemically the same as the drug prescribed.
- Data Collection Site(s):** MOH, Board of Pharmacy
- Data Collection Methodology:** Document review and interviews to determine the existence of a law or written regulation that allows generic drugs to be dispensed in place of brand name drugs. Note which settings are covered by this law or regulation. This indicator scores only the existence of such law(s) or regulation(s), not whether substitution of generic for proprietary drugs is actually practiced.
- Computation & presentation:** Score the indicator according to the following categories:
- a. Generic substitution is legal in both private and public sector settings
 - b. Generic substitution is legal in public sector settings only
 - c. Generic substitution is legal in private sector settings only
 - d. Generic substitution is explicitly illegal
 - e. No regulations covering generic substitution exist
- Example:** In country Y, only pharmacists practicing in public sector facilities are legally allowed to substitute generic equivalents unless specifically indicated otherwise on the prescription.

B. *Formulary/Essential Drugs List***B.1. Number of drug products on National Drug Formulary List (C)**

- Purpose:** To assess whether National Drug Formulary List (NDF) exists, and to determine the number of generic products it contains (unique as to chemical components, strength & dosage form, and route of administration).
- Definition:** A NDF is defined as a list containing all drugs approved for routine use in public sector facilities. In some countries the NDF may apply to both public and private sectors. It may be known as a National Essential Drugs List.
- Data Collection Site(s):** MOH, CMS
- Data Collection Methodology:** Determine if a NDF exists. If so, study organizers must acquire copies of the published NDF to assess the number of drug products it contains. To count the number of drugs accurately, procedures must be developed for determining whether or not any brand name products listed are chemically equivalent to others appearing in generic form on the formulary list, since for this indicator both brand name and generic products would be considered functionally identical. Note that when counting products, different strengths of the same chemical entity count as different products. For example, tetracycline 250 mg. tablets and tetracycline 500 mg. tablets are counted as 2 products. If, however, the country uses both tablets and capsules of the same product at the same strength interchangeably, then they are counted as one product. For example, ampicillin 250 mg tablets and ampicillin 250 mg capsules are counted as one product.
- Computation & Presentation:** Indicator is recorded as the total number of unique, generic drug products on the list. If no NDF exists, this indicator would be recorded as N/A.
- Example:** Country A possesses a National Drug Formulary. The total number of unique, generic drug products listed is 230.

B.2. Existence of a Sub-set Essential Drugs List (C)

Purpose:	To determine whether an officially adopted and published Primary Health Care Essential Drugs List (PHC EDL) exists which is a subset of the National Formulary, and to count the number of generic products it contains (unique as to chemical components, strength & dosage form, and route of administration).
Definition:	A PHC EDL is defined as a list of drugs that has been prepared and officially approved by national authorities to enumerate those drugs that are approved for routine use in primary health care facilities.
Data Collection Site(s):	MOH
Data Collection Methodology:	Determine if a PHC EDL exists. If so, acquire copies of the published list. Develop procedures for determining whether or not any brand name products on the list are chemically equivalent to other products appearing on the list in generic form, since for this indicator, both brand name and generic products would be considered functionally identical. Note that when counting products, different strengths of the same chemical entity count as different products. For example, tetracycline 250 mg. tablets and tetracycline 500 mg. tablets are counted as 2 products. If, however, the country uses both tablets and capsules of the same product at the same strength interchangeably, then they are counted as one product. For example, ampicillin 250 mg tablets and ampicillin 250 mg capsules are counted as one product.
Computation & Presentation:	This indicator is recorded as either <i>yes</i> or <i>no</i> . When a Sub-set Essential Drug List does exist, and the indicator is <i>yes</i> , record the year in which the list was published and the number of products it contains.
Example:	In country B, a PHC EDL was officially adopted and published in 1989, it contains 212 drugs.

B.3. Existence of a National Drug Formulary Manual providing basic drug information for prescribers, revised within the past 5 years (C)

- Purpose:** To determine whether a source of accurate, unbiased, and reasonably current information for prescribers about the drugs on the National Drug Formulary has been produced or revised by the MOH within the past 5 years.
- Definition:** To qualify as a National Formulary Manual, the description of drugs should include at least: chemical components, indications, contraindications, side effects, and recommended dosages. This information must have been reviewed and revised within the previous five years.
- Data Collection Site(s):** MOH
- Data Collection Methodology:** A National Drug Formulary must exist for this indicator to be meaningful. If so, obtain the most recent copy of any Formulary Manual that has been prepared to provide impartial information about the drugs on the National Formulary List. Determine if the information in the manual meets all the criteria specified in the definition.
- Computation & Presentation:** Indicator is scored either "yes" or "no" depending on whether a National Formulary Manual exists which meets the required criteria. The indicator is scored as "no" if (1) a manual has been produced with the specified information; or (2) a manual has been produced or revised within 5 years, but information is incomplete; or (3) a manual is being produced or is available only in draft version. In any of these cases the situation should be described.
- Example:** In country Y, a national formulary manual exists; it was revised June 1989.

B.4. Presence in public sector health facilities of an edition of the National Formulary Manual or Essential Drug List Manual, revised within the last five years (R & P)

Purpose: To indicate the extent to which copies of the current edition of the National Formulary Manual (NFM) or Essential Drugs List Manual (EDLM) specific to a particular level of patient care, are available at the local level.

Definition: This indicator measures the presence of the National Formulary Manual or EDL Manual at facilities visited during the survey.

Data Collection

Site(s): Health facilities

Data Collection

Methodology: A NFM and/or EDLM must exist for this indicator to be meaningful. The staff must be able to produce a copy of the current edition of this formulary manual. Select a sample of at least 20 facilities. For each facility visited, record whether or not the manual is physically present. If no NFM is present, the indicator should be scored 0 for that facility.

Computation &

Presentation: Indicator is a percentage, computed as the number of facilities at which the appropriate Formulary Manual is found, divided by the total number of facilities in the sample, multiplying by 100.

$$\begin{array}{l} \% \text{ Facilities with } = \text{ Number Facilities with } \times 100 \\ \text{Formulary Manual} \quad \frac{\text{Formulary Manual}}{\text{Number Facilities in Sample}} \end{array}$$

Example: During an indicators study in Country A, only 20% of health facilities visited were able to produce a copy of the National Formulary Manual.

B5. Existence of a drug information center which is officially recognized by the Ministry of Health

Purpose: To assess whether there exists an operational drug information center recognized by the Ministry of Health.

Definition: A drug information center should maintain and provide current information for policy makers, prescribers, pharmacists and consumers on such topics as indications, contraindications, dosage, adverse reactions, costs and sources, storage requirements, and actions to take for inadvertent administration and over doses. This indicator is defined as the number of functioning information centers which are officially recognized by the MOH.

Data Collection

Site(s): Drug Regulatory Authority, MOH, schools of medicine or pharmacy

Data Collection

Methodology: Use interview with key informants to identify drug information centers. Follow up with brief visits to each site. Collect the following information:

- Location of the center and affiliation (i.e., university, MOH, etc.).
- Principal users, for example, Drug Regulatory Authority drug registration staff; hospital staff, medical students or the general public.
- Services offered.
- Documented demand/quantity of services approved.
- Types of equipment and information resources available...scope and currency.
- Numbers and qualifications of staff
- Source of funding.

Computation & Presentation:

The indicator is presented as the number of officially recognized information centers. Describe any existing drug information centers, providing the following information described above.

Example:

In country Q, there is one official drug information center. It is located in the College of Pharmacy, and serves the University, the MOH, and the Board of Pharmacy. The center responds to requests, and provides an irregular newsletter on new drugs. This is staffed by one pharmacist, who has no formal training on drug information. The center has a typewriter but no computer. The information resources consist of twelve texts; the newest is five years old. Funds for the center are obtained from the MOH. Funds for resource acquisition are budgeted, but never spent. Information demand is not documented.

C. Public Sector Budget and Finance

C.1. Public sector expenditures or budget on pharmaceuticals, US\$ per capita (C)

- Purpose:** To estimate in per capita terms the total value of MOH pharmaceutical expenditures or budget during the previous year, which provides a rough global measure of the adequacy of expenditure on pharmaceuticals in the public health system.
- Definition:** Public sector per capita expenditures are defined as the total amount of money (in US\$ at the current rate of exchange) spent on pharmaceuticals by all public sector sources (national, regional and local budgets combined) for the most recent financial year, per individual in the population. Public Sector budget is defined as the budget for pharmaceutical purchases which was approved (not the requested budget). In many countries, only the approved budget figures will be readily available.
- Data Collection Site(s):** MOH, Ministry of Finance, other relevant public sector budgetary sources
- Data Collection Methodology:** In most countries, the Ministry of Finance publishes an annual report on budgets and expenditures. Through interviews with relevant government officials and examination of historical documents obtain a complete accounting of total budget or expenditures on pharmaceuticals in the previous fiscal year, including valuation of donated products if their value was accounted for in the forward planning budget. This estimate must include budget or expenditures from all public sources at the central, regional, and local levels. Finally, obtain a reasonably reliable estimate of the current national population from the Bureau of Statistics or some other official source. If current population estimates are unavailable, get the last census figure, year it was done, and population growth rate per year, or use figures from the latest edition of the *World Development Report*. The value of donated pharmaceuticals should be included only if the value of donations was counted as a line item in the forward planning budget and/or reports of actual expenditures. If there is information about major public drug purchasing systems outside the MOH, such as Social Security or the Armed Forces, this data should be presented separately.
- Computation & Presentation:** The indicator is computed by dividing the total value of public sector drug budget or expenditures for the most recent financial year (expressed in US\$ at the current rate of exchange) by the national population. Be sure to stipulate whether the value is budget or actual expenditure.

Public Sector

$$\text{Drug Budget per capita} = \frac{\text{Total Value of Public Sector Drug Budget}}{\text{National Population}} \times 100$$

Public Sector

$$\text{Drug Expenditure per capita} = \frac{\text{Total Value of Public Sector Expenditure}}{\text{National Population}} \times 100$$

Example:

In Country A, the actual expenditure on pharmaceuticals in the last fiscal year was US\$ 3,000,000. In addition, there was a donation of drugs from the World Health Organization worth US\$ 1,300,000, and a credit from a bilateral donor worth US\$ 500,000, giving a total figure of US\$ 4,800,000 worth of expenditure on pharmaceuticals in the last fiscal year. In this country, last census was done 9 years ago, reporting a population of 3,430,000, and an average population growth rate of 2.5% / year. Thus a reasonable estimate of current population is $(3,430,000) \times (1.025)^9$ or 4,283,600, which in turn gives a per capita annual expenditure of US\$ 1.12.

C.2. Existence of a system for recovering costs of drugs dispensed in the public sector (C)

Purpose:	To note the presence or absence of a system for recovering from patients part or all of the costs of drugs dispensed in public sector health facilities.
Definition:	For purposes of this indicator, a cost recovery system is defined as any system which supports drug supply costs by charging patients for all or part of the costs of the drugs dispensed to them.
Data Collection Site(s):	Ministry of Health or Ministry of Finance
Data Collection Methodology:	Many countries have systems or mechanisms for charging patients for the drugs which they receive. These are known by such names as "revolving funds," "drug sales programs," and "cost recovery systems." In some cases the objective is to recover all costs associated with acquisition, storage, distribution and dispensing of drugs. More often, the objectives are to recover some part of these costs, say 50%. When partial cost recovery is the goal, the term "cost sharing" is often used. Charges to patients may be fixed in a number of ways including full acquisition cost, plus a margin for management; or fixed fees for prescriptions, regardless of individual product costs. A system in which all or part of a fee charged to patients is specifically designated for future drug purchases should be considered a drug cost recovery system. A system in which patients are charged fees for medical consultations, with no provision that the revenues be used for purchasing new drugs should not be considered a drug cost recovery system for purposes of this indicator (even though some of this income may be used for purchasing drugs). Use interviews with key informants to determine whether or not the Ministry of Health has a drug cost recovery system. Obtain documentation as to the official cost recovery policy and rates.
Computation & Presentation:	<p>This indicator is expressed as "yes" for the presence of a drug cost recovery system, and "no" for the absence. Where systems exist, attempt to describe them in terms of the following criteria:</p> <ol style="list-style-type: none"> Financial objectives, such full or partial cost recovery. Percentage of all health facilities in which cost recovery activities take place. Fee structure. Percentage of drug purchase costs which are recovered.
Example:	In country Q, cost recovery schemes operate in all of MOH's 36 national and regional hospitals, but not in the 122 health centers. There is no fixed financial goal concerning the percentage of costs to be recovered, but it is clear that the expectation is partial cost recovery, or cost sharing, and not total cost recovery. Patients are charged flat fees for each different drug product they receive, but the structure is differential: 1 Peso for "ordinary" drugs and 2 Pesos for "expensive drugs." There are no national figures for the amounts of money taken in, but data

available for the Western Region indicated that revenues from drug sales at the 6 hospitals was P 900,000 which represents 25% of the cost of the region's hospital drug purchases for FY 1992 and 15% of all drug purchases.

C.3. Percent of patients paying a charge for drugs in public sector health facilities (P)

Purpose: To estimate the percentage of patients who are contributing to payment of drug costs, as an indicator the functionality of drug cost recovery systems.

Definition: The definition of "patient who pays a charge" is any observed patient encounter in which the patient pays a charge (no matter how large or small) specifically related to drugs which are dispensed.

Data Collection

Site(s): A sample of health care facilities wherein drug cost recovery activities are supposed to take place.

Data Collection

Methodology: The theory and practice of operating drug cost recovery systems can vary greatly. It sometimes happens that Ministry's of Health have stated policies of charging for drugs, but in practice do not enforce these policies in health care facilities. Taking a measure of the percentage of patients who actually make some payment gives some indication of whether cost recovery schemes function in reality. Data for this indicator are collected retrospectively or prospectively as follows: In a sample of 20 health facilities review or observe drug dispensing for 30 patients. This gives a sample of 600. At each site, record the number of patients who pay a charge for the drugs they receive, and the number that do not. (If a fee is paid for medical services (with drugs included) this does not count for this indicator).

Computation &

Presentation: The percentage of patients paying a charge is calculated by dividing the total number of patients paying a charge, by the total number of patients observed, and multiplying by 100.

$$\% \text{ Patients Paying a Charge} = \frac{\text{Total Number Patients Paying Charge}}{\text{Total Number Patients Observed in Sample}} \times 100$$

Example: In country Q, drug dispensing was observed at a sample of 20 health care facilities. Out of 600 patients observed at the dispensing point, 42% paid a charge for the drugs they received.

C.4. Percentage of total government recurrent budget used for Ministry of Health (C)

Purpose: To estimate the proportion of total government recurrent budget which is consumed by the Ministry of Health.

Definition: The recurrent budget normally excludes capital costs (and in some cases, excludes donations). This indicator is defined as the percentage of the total government recurrent budget, which is provided for use by the MOH, in the most recent fiscal year for which information is available, which is provided to the MOH recurrent budget.

Data Collection

Site(s): MOH, Ministry of Finance, Official Budget Book

Data Collection

Methodology: Normally this data is collected from the most recent report on recurrent expenditures which is published by the Ministry of Finance. If such a report has not been published, contact senior officials at the MOH and /or the Ministry of Finance to obtain necessary information. If the information is only estimated, stipulate this with recording the data. Be sure to avoid confusion between amounts requested and amounts allocated. The amount allocated is the relevant number. If information is available for actual expenditures, use this information for comparison with allocations. See next indicator discussion for relevant information.

Computation &

Presentation: The indicator is recorded as a percentage, calculated as total Ministry of Health budget, divided by total government recurrent budget, multiplied by 100.

$$\% \text{ Total Government recurrent budget for MOH} = \frac{\text{Total Ministry of Health Budget}}{\text{Total government recurrent budget}} \times 100$$

Example: In 1992, Country B devoted 6.0% of its total budget to the Ministry of Health.

C.5. Percentage of total Ministry of Health recurrent budget used for pharmaceuticals (C)

Purpose: To measure the proportion of total recurrent Ministry of Health recurrent budget consumed by pharmaceuticals.

Definition: The recurrent MOH budget is defined in the previous indicator. The amount used for pharmaceuticals is that amount allocated for purchase of pharmaceuticals in the same budget year. As is the case with the previous indicator, actual expenditures can be used if both values (recurrent MOH budget and allocation for pharmaceuticals) represent actual expenditures rather than budget.

Data Collection

Site(s): MOH / Ministry of Finance

Data Collection

Methodology: Normally this data is collected from the most recent report on recurrent expenditures which is published by the Ministry of Finance. If such a report has not been published, contact senior officials at the MOH and /or the Ministry of Finance to obtain necessary information. If the information is only estimated, stipulate this with recording the data. Be sure to avoid confusion between amounts requested and amounts allocated. The amount allocated is the relevant number. If information is available for actual expenditures, use this information for comparison with allocations. See previous indicator discussion for relevant information.

Computation &

Presentation: The indicator is recorded as a percentage, calculated as the MOH budget for pharmaceuticals, divided by total Ministry of Health Budget, multiplied by 100.

$$\begin{aligned} &\% \text{ MOH Budget} \\ &\text{used for pharmaceuticals} = \frac{\text{MOH budget for Pharmaceuticals}}{\text{Total MOH Budget}} \times 100 \end{aligned}$$

Example: In the 1993 fiscal year, Country B devoted 34.8% of its Ministry of Health budget to pharmaceuticals.

D. Public Sector Pharmaceutical Procurement**D.1. Existence of policy to limit public sector pharmaceutical procurement to items on the National Formulary or Essential Drugs List (C)**

Purpose: To assess whether a policy exists restricting pharmaceutical procurement for the public sector, to drugs which are listed on the National Drug Formulary or Essential Drug List.

Definition: A written official policy restricting public sector procurement to items included in the officially approved national public sector drug list (National Formulary or EDL)

Data Collection

Site(s): MOH, Procurement Agency

Data Collection

Methodology: Obtain a copy of a written public sector procurement policy related to the purchase of products not on the national public sector list. The indicator measures only if such a policy exists, not whether it is actually followed.

Computation &

Presentation: The indicator is scored "yes" if only drugs on the national EDL are eligible for public sector procurement, and "no" if a national formulary or Essential Drug list does not exist, or if procurement is not restricted to drugs on the list.

Example: In country X, a national EDL exists, but public sector pharmaceutical procurement is not limited to this list.

D.2. Coverage by a centralized system for routine procurement of public sector drugs (C)

Purpose: To assess whether a central (national, or in some larger countries, a state by state) system exists for routine procurement of public sector drugs, which is one mechanism for rationalizing drug purchasing and obtaining economies of scale in drug prices.

Definition: The "central system" is an officially mandated procurement mechanism via a centralized agency, authority, or ministry office.

Data Collection

Site(s): Procurement Unit at MOH, other Government ministry, or parastatal agency

Data Collection

Methodology: Assess whether a centralized procurement system exists, and assess the approximate percentage by volume/value of public sector drugs procured via this system. Data is obtained from procurement records for the most recent year for which data is available. If data on total procurement is not reliable in situations where extensive local facility purchases occur, this may be estimated, but this should be stipulated. The following data is needed:

- Total value of drugs procured by or for MOH. If more than one agency or institution purchases drugs, provide separate value purchased by each.
- Value of drugs purchased by Central Procurement Agency.

Computation &

Presentation: Estimate the percentage by value of drugs purchased through the central procurement system, computed by dividing the value of drugs centrally procured by the total value of drugs purchased in the MOH, multiplied by 100.

% by value of = $\frac{\text{Value of Drugs centrally procured}}{\text{Total Value of Drugs Purchased in MOH through Central Procurement System}} \times 100$

Example: In country Y, central drug procurement is done by the Central Medical Stores; in 1992, 80% of total drug purchases were made by the CMS.

D.3. Percentage of average international price paid for last regular procurement (of a set of tracer drugs) (C/R/P)

Purpose: To measure the relative cost of drug procurement in comparison to the average international price at a given point in time, as measured for a set of tracer drugs.

Definition: Average international price is the average FOB price from set of international supplies. One source is the MSH International Price Guide. Last regular procurement price is that C.I.F. price paid during the last regular procurement.

Data Collection

Site(s): MOH - Procurement Unit or Central Medical Store; Regional Administration or Medical Store

Data Collection

Methodology: A set of tracer drugs for which this indicator will be measured must be developed as one of the preparatory activities for the indicator study (see Annex 1). Information on C.I.F. prices paid by MOH for the tracer drugs should apply to the last regular procurement. Any more recent ad hoc or emergency procurement that may have taken place should be compared separately to international prices. The average international prices for the indicator drugs should be determined by reference to average international prices in the MSH International Drug Price Indicator Guide; the average price in this guide is FOB, and should be adjusted upward by 20% to reflect average shipping costs. Specify the source of international prices and the year of both data sets. If all purchases are not done by one central agency, compile information separately by type of institution, and compute the percentage of international price for each type of purchasing institution (i.e., Regional Medical Stores, Hospitals, Health Centers, etc).

Computation & Presentation:

The indicator should be presented as an average of the percentages of international price for the set of tracer drugs. If data is collected from different levels of the system, a separate average should be calculated for each level. Percentages are computed by dividing purchase cost of the identified drugs at last regular procurement by the average international price in the most recent Drug Price Guide, multiplying the result by 100.

$$\text{Percentage of Average International Price} = \frac{\text{Facility Unit Price}}{\text{(Average International Unit Price)}} \times 100$$

Example: In country C, the average procurement price for the set of tracer drugs was 127% of average international price in 1992 for purchases made through the central procurement agency. For direct hospital purchases, the average procurement price was 206% of average international price.

D.4. Percentage of MOH drugs centrally purchased through competitive tender (C/R/P)

Purpose: To describe whether routine drug procurement at central level is typically carried out using a process that encourages competitive cost efficiencies.

Definition: To be considered a formal competitive tender process, pharmaceuticals must be purchased on the basis of sealed bids submitted in response to publicly offered government requests to supply drugs. The tender process may be open (such as ICB) or closed, with or without prequalification of vendors.

Data Collection

Site(s): MOH / Other central procurement agency, Medical Stores, Health Facilities (if procurement is decentralized)

Data Collection

Methodology: For this indicator to make sense, the MOH must use competitive tenders. Collect data on the total value of all drugs purchased during the last fiscal year, and on the value of drugs purchased through formal competitive tenders. Information may be available from a central purchasing agency; in many cases, information must be compiled based on data from the health facilities which are visited.

Computation &

Presentation: The indicator is a percentage, estimated or calculated by dividing the total value of drugs purchased through competitive tender (in the previous fiscal year) by total value of all drugs purchased, then multiplying the result by 100.

$$\% \text{ Drugs Purchased through Competitive Tender} = \frac{\text{Total Value of Drugs Purchased through Competitive Tender}}{\text{Total Value of all Drugs Purchased}} \times 100$$

Example: In country A, in the Financial Year 1990/1, 60% of the drugs (by value) procured by the MOH were purchased through competitive tender.

E. Public Sector Pharmaceutical Logistics**E.1. Percent of inventory variation in the stock record keeping system (C/R/P)**

Purpose: To measure the degree of functionality of the Management Information System (MIS) used to control drug inventory at central (and regional) stores.

Definition: Average inventory variation is the weighted average difference between recorded stock levels and actual physical stock count. This is also known as average piece variation.

Data Collection Site(s): Central Medical Stores, Regional Level Stores (if applicable), and Health Facilities.

Data Collection Methodology: This indicator is based on the list of 20-25 tracer drugs used to treat common health problems (see Annex 1). Make sure that you have some items in this list which are likely to be stored together in health facilities (e.g., insulin injections, Ringer's Lactate, penicillin injection). Visit the CMS (and at least one regional store if they exist in this system), and a sample of 20 health facilities. Ask staff to produce the most accurate estimate of current stock level of each of the tracer drugs. Ask them to adjust their numbers for any recent issues which have not been entered in their records. Take note of the means used to produce these estimates (computerized system, manual ledgers, bin cards). If bin cards exist, and if they were not used to produce the best estimates, obtain a second set of estimates based on bin cards. Finally, carry out a physical count of stock levels for these drugs.

Computation & Presentation: Calculate the weighted average of percent differences. To do this, divide the sum of all units of all tracer drugs indicated to be in stock according to the record keeping system, by the sum of all units actually found to be in stock according to the physical count. Multiply the result by 100.

$$\text{Average Percent Difference} = \frac{\text{Total of All Units Recorded}}{\text{Total of All Units Counted}} \times 100$$

*Note: Units should be the same type.

Compute this average for each facility, showing data in tables, one table for each type of facility visited. Present the averages separately for:

- a. Central Medical Stores
- b. Regional Medical Stores
- c. Health Facilities

Example: After adjusting for issue tickets not yet entered in records, at the Central Medical Stores in country B, the average percentage variation between physical stock on hand and stock recorded on bin cards was 10%; however, the average variation between the computerized MIS and physical stock was 16%. In 20 health facilities, the average variation was 27%.

E.2. Percentage of records that correspond with physical counts (C/R/P)

Purpose: To measure the degree of functionality of the Management Information System (MIS) used to control drug inventory at central (and regional) stores and at health facilities. This indicator is used with the average inventory variation to measure the functionality of inventory records. This indicator softens the impact in cases where average variations are skewed by large variations in a small number of items.

Definition: This is the percentage of tracer drug inventory records which corresponds exactly with physical stock count.

Data Collection

Site(s): Central Medical Stores, Regional Level Stores (if applicable) and Health Facilities

Data Collection

Methodology: This indicator is based on the list of 20-25 tracer drugs used to treat common health problems (see Annex 1). Make sure that you have some items in this list which are likely to be stored together in health facilities (e.g., insulin injections, Ringer's Lactate, penicillin injection). Visit the CMS (and one regional store if they exist in this system), and ask staff to produce the most accurate estimate of current stock level of each of the tracer drugs. Ask them to adjust their numbers for any recent issues which have not been entered in their records. Take note of the means used to produce these estimates (computerized system, manual ledgers, bin cards). If bin cards exist, and if they were not used to produce the best estimates, obtain a second set of estimates based on bin cards. Finally, carry out a physical count of stock levels for these drugs.

Computation &

Presentation: Calculate for the list of tracer drugs the percentage of records checked which correspond exactly with the physical counts. To do this, divide the number of records for which no discrepancy was found by the total number of records checked, and multiply the result by 100.

Example: After adjusting for issue tickets not yet entered in the records at the Central Medical Store in country Q, the percentage of records for 25 tracer drugs that corresponded exactly with physical counts was 90%.

E.3. Availability in public sector health facilities of a set of un-expired tracer drugs used to treat common diseases (C/R/P)

Purpose: To measure the availability of important tracer drugs recommended for treating common diseases at a given point in time in medical stores and health facilities.

Definition: A drug is defined as available if even one unit of unexpired product is in stock.

Data Collection

Site(s): Central Medical Stores, Regional Stores (if applicable) and Health Facilities.

Data Collection

Methodology: This indicator is based on the list of 20-25 tracer drugs used to treat common health problems developed by study organizers (see Annex 1). First, in consultation with staff at local health facilities, determine which of these products are normally stocked. Then, assess whether each of the listed drugs is available. If any of the indicator drug is available (1 tin, 1 box, 1 tray of vials) and it is unexpired record that item as present even if it is likely to be out of stock very soon. If all drug stock is expired record 0. Do not worry about stock levels.

Computation &

Presentation: The indicator is recorded as a percentage, calculated by dividing the number of specified products found in stock by the total number of drugs for which availability was assessed, and multiplying by 100. For the survey as a whole, the indicator is calculated as the average of these facility-specific percentages.

$$\text{Drug Availability} = \frac{\text{Number of Tracer Drugs In Stock}}{\text{Total Number of Tracer Drugs}}$$

Present the data in separate tables for each type of facility visited.

Example:

In a survey of 20 health facilities -- where 19 tracer products were listed as normally-stocked -- an average of 80.7% of the listed products was found in stock, range among facilities being 25 to 85%, the lower range being associated with more peripheral health facilities, as follows:

- Regional medical stores - 85 %
- District hospitals - 64 %
- Health centers and posts - 48 %

E.4. Average Percentage of time out of stock of a set of tracer drugs (C/R/P)

Purpose:	To measure the prevalence of stockout by determining the amount of time they have been out of stock over a defined period (usually the 12 months prior to the month of visit).
Definition:	This indicator measures the stock status for indicator drugs over the 12 months prior to the visit.
Data Collection Site(s):	Central Medical Stores, Regional Stores, Health Facilities.
Data Collection Methodology:	To be considered a stockout, there must be none of a drug in stock at the time when the survey is conducted. If even small quantities of a drug are present, the drug should be counted as in stock. Stockout duration is defined as the percentage of days during the previous calendar year that a drug has been out of stock (based on inventory records). This indicator is based on the list of 20-25 tracer drugs used to treat common health problems developed by study organizers (see Annex 1). In order to determine stockout duration, it is necessary that there be a reasonably accurate manual inventory recording system (ledger/bin cards), and that stock management be done appropriately. First determine which of these products are normally stocked in each health facility. This is done, as for the previous indicator, in consultation with staff at local health facilities. For determining average stockout duration, identify which of the listed drugs were out of stock in last year, and then determine for how many days the product was out of stock, during the last 12 months for which records are updated (ideally the 12 months prior to the month in which the visit occurs).
Computation & Presentation:	<p>Enter the current and historical stock data into a matrix showing the names of the indicator drugs, the number of stockouts at the time of the survey, and the number of days of stockout in the previous year. Compute for each drug on the list the percentage of days out of stock during the past year by dividing the number of days out of stock by 365, and multiplying by 100. Finally, compute across all drugs out of stock the average percentage of days out of stock in each facility. Compute an average for all tracer drugs at a facility by adding the days out of stock for all tracer drugs, dividing this by the number of tracer drugs, then dividing by 365 and multiplying by 100.</p> <p>Present data in tables, and report averages for each type of facility visited.</p>
Example:	In country C, an average of 15% of the indicator drugs were out of stock at the Central Medical Stores at the time of survey. Over the preceding 12 months, 20% of the drugs were out of stock at least once in this CMS, the average percentage of days out of stock among these being 32%.

E.5. Number and value of expired drug products in stock (C/P)

Purpose: To measure the prevalence and impact of losses due to expired drugs.

Definition: The number of drug products found to be expired, and the value of those products, determined by inspection of physical stock and/or records of expired stock.

Data Collection

Site(s): Warehouses and health facilities

Data Collection

Methodology: This indicator is based on inspection of records and physical stock to determine if any expired drug products are in stock at the facility. The value of the expired stock is determined according to the price paid at last purchase (or as shown in inventory records). If records of expired stock are kept, the number and value of expired stock should be recorded. Whether or not these records are kept, physical stock should be examined for expired stock during the process of checking actual stock against inventory records.

Computation &

Presentation: The indicator is recorded as the number of expired drug products found, and as the value of those products. The number is based on each expired drug product counting as one (no matter what quantity is in stock). The quantity of each expired product is also recorded, in order to compute the value of expired stock. The value is computed by multiplying the quantity of expired product by the last purchase price recorded in procurement records or files, or by the latest cost price recorded in inventory records. The source of price information should be noted.

Number of expired drugs = Number of drug products in stock with at least one expired unit.

Value of Each Expired Drug = Quantity of drug multiplied by last recorded cost price.

Total value of expired drugs = Sum of values of each expired drug.

Example: In a survey of 20 health facilities, 39 drug expired drug products were found, with a total value of \$11,200. Expired drug products were found in 7 of the 20 facilities.

F. Drug Utilization and Patient Access**F.1. Population per public health facility which dispenses drugs (C)**

Purpose: To estimate the coverage public sector facilities which provide drugs, (such as tertiary care hospitals, secondary care hospitals, primary care hospitals and health centers, or lower level primary care facilities) which is one rough measure of overall patient access to public sector pharmaceutical services.

Definition: The indicator measures the population which, must be covered, on average, by each public sector health facility considering the total of all hospitals, health centers and dispensaries and using a reasonably reliable estimate of the national population.

Data Collection

Site(s): MOH

Data Collection

Methodology: Obtain a list of all functioning public sector health facilities (all levels) in the country as a whole. Obtain also official information about the most recent estimate of national population. If even the most recent estimates available locally are not current, get the last census figure, year it was done, and population growth rate per year (or use the most recent edition of the *World Development Report*).

Computation & presentation:

The indicator is a ratio, obtained by dividing the total national population by the number of (functioning) MOH health facilities which dispense drugs.

Example: In country X, a total of 200 public sector health facilities are functioning. With a total population of 10,000,000 people, this yields an average of 50,000 people per public sector health facility.

F.2. Average number of drugs prescribed per curative outpatient encounter (P)

Purpose: To measure the average number of drugs prescribed per outpatient encounter in outpatient facilities, since too high (or too low) an average number prescribed can indicate poor prescribing practices.

Definition: This indicator measures the average number of drugs prescribed per outpatient per encounter, where each drug written separately is counted as a separate drug prescribed and where encounters include only visits by patients seeking curative care.

Data Collection

Site(s): Twenty Public Sector Health facilities (although this could be measured at NGO and private sector facilities)

Data Collection

Methodology: Select a sample of 30 patient encounters at each facility, either retrospectively from medical records or prospectively from patients attending on the day of the survey, and count the number of drugs prescribed to each patient. (See description of sampling methods in section on Data Collection Strategies). Include only patients seeking curative care. To count drugs in a uniform way in some settings, guidelines must be established for enumerators on how to count certain ambiguous prescribing practices, for example, locally compounded multi-drug combination therapies, or certain combined oral/injection therapies, such as a standard treatment of injection followed by oral administration. The methods for collecting these indicators are also described in the manual published by WHO.⁶

Computation &

Presentation: The indicator is recorded as an average, calculated by dividing the number of different drug products prescribed by the total number of patient encounters surveyed (remember to include those curative encounters in which no drug was prescribed). The overall indicator is an average of these facility-specific averages. Along with this average, provide average and range figures. If different levels of the system are visited (i.e., hospitals, health centers and health posts), tabulate results separately and summarize with averages for each type of facility.

$$\text{Average Number of Drugs} = \frac{\text{Total Drugs Prescribed}}{\text{Total Encounters Studied}} \times 100$$

Example: An indicators survey of health centers in Country A found that patients are prescribed an average of 1.4 drugs per curative encounter. The range among facilities was from 0.9 to 2.8 drugs per encounter.

F.3. Percentage of drugs prescribed by generic name (P)

Purpose: To measure the tendency of prescribers to prescribe by generic name, rather than by proprietary name.

Definition: This indicator measures the percentage of drugs which are prescribed using their correct generic names, as identified in the WHO List of International Non-proprietary Names.

Data Collection

Site(s): Twenty Health facilities

Data Collection

Methodology: Study organizers must develop a list of (or an explicit way of defining) the specific product names to be included as generic drugs; usually the generic names of drugs are identified on the National Formulary List. Select a sample of 30 patient encounters at each facility, either retrospectively from medical records or prospectively from patients attending on the day of the survey, and observe the way each drug prescribed in this sample was written. (See description of sampling methods in section on Data Collection Strategies). Include only patients seeking curative care. Enumerators must be able to observe the actual names used to describe the drugs prescribed, as opposed to having access only to the names of the products dispensed.

Computation & Presentation:

The indicator is recorded as a percentage, computed by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, and by multiplying by 100. The overall indicator is an average of these facility-specific percentages. Along with this average, provide range figures.

$$\% \text{ Generic Prescribed} = \frac{\text{Total Drugs Prescribed by Generic Name}}{\text{Total Number of All Drugs Prescribed}} \times 100$$

If different levels of the system are included, summarize the results in separate tables for each type of facility.

Example: In 15 health centers in Country A, an average of 36% of drugs were prescribed by generic name, while in 5 hospitals in the same country, 43% of prescribed drugs were written using their generic names. The range among facilities varied between 15% to 80%.

F.4. Percentage of outpatients receiving injections (P)**F.5. Percentage of outpatients receiving antibiotics (P)**

Purpose: To measure the overall level of use of two important, but commonly overused and costly forms of drug therapy.

Definition: Injectable drugs are those given intravenously or intramuscularly, with the exception of EPI vaccines. All antibacterials, penicillins, anti-infective dermatologicals, ophthalmic anti-infectives, and anti-diarrheal drugs containing antibiotics should be included as antibiotics. Metronidazole and anti-tuberculosis drugs (except streptomycin) would not be considered antibiotics. The indicator measures the percentage of outpatient curative encounters which receive these therapies. The indicator would be misleading if inpatients and outpatients encounters are mixed.

Data Collection

Site(s): Twenty Health facilities

Data Collection

Methodology: Before the study, organizers should develop a list of which medications are to be counted as antibiotics to be used as a reference by data collectors. Select a sample of 30 patient encounters from each facility, either retrospectively from medical records or prospectively from patients attending on the day of the survey, and count the number of drugs each patient receives. (See description of sampling methods in section on Data Collection Strategies). Include only outpatients seeking curative care. Count separately the number of patients who are prescribed one or more antibiotics, or one or more injections. If a patient receives two or more antibiotics or injections, this still counts as one instance for this purpose.

Computation &

Presentation: Both indicators are recorded as percentages, computed by dividing the number of patient encounters during which an antibiotic is prescribed/an injection is given, by the total number of patient encounters surveyed, and multiplying by 100. The overall indicators are the averages of these facility-specific percentages. Along with this average, provide average and range figures.

$$\begin{array}{l} \% \text{ of Patient} \\ \text{Injections} \end{array} = \frac{\text{Total \# of Patients Prescribed Injections}}{\text{Total Number of Patient Encounters Surveyed}} \times 100$$

$$\begin{array}{l} \% \text{ of Patient} \\ \text{Antibiotics} \end{array} = \frac{\text{Total \# of Patients Prescribed Antibiotics}}{\text{Total Number of Patient Encounters Surveyed}} \times 100$$

Example:

In a survey of 20 facilities in Country Z, 27.3% of all outpatient encounters received one or more antibiotics. The average percent of encounters in which one or more antibiotics was prescribed was 27.3%, with the range among facilities being from 0% to 56.7%. An injection was given during 13% of all consultations. The average percent of encounters in which an injection was prescribed was 10%, with the range among facilities being from 0% to 56.7%.

F.6. Percentage of Prescribed Drugs Which are Dispensed

Purpose: To measure the degree to which health facilities are able to provide the drugs which were prescribed.

Definition: Drugs which are actually dispensed are defined as drugs which are prescribed and dispensed from the health facility.

Date Collection

Site(s): Twenty Health Facilities

Data Collection

Methodology: If records document which drugs were not dispensed, this indicator can be collected retrospectively. Otherwise, observe 30 dispensing encounters. Each drug counts separately. If any portion of the prescribed amount is dispensed, count the drug as dispensed.

Computation &

Presentation: Percentage, calculated by dividing the number of drugs actually dispensed at the health facility by the total number of drugs prescribed, multiplied by 100.

$$\begin{array}{l} \text{\% of Prescribed} \\ \text{Drugs which} \\ \text{are Dispensed} \end{array} = \frac{\text{Number Drugs Dispensed}}{\text{Number Drugs Prescribed}} \times 100$$

Example: In health facility N, 73% of prescribed drugs were actually dispensed at the health facility.

G. Product Quality Assurance**G.1. Number of drug products tested by the Ministry of Health during the past year (C)**

Purpose: To determine how actively the Ministry of Health pursues drug product quality testing. Typically, Ministries of Health have laboratory analysis conducted on drug samples on such occasions as: receipt of bids from potential suppliers; arrival of new stock at the central warehouse; submission by hospital pharmacies on suspicion of problems; or random sampling in retail pharmacies.

Definition: This indicator measures the number of separate drug products which were submitted by MOH facilities for testing within a recent 12 month period, and the number of products for which results were obtained.

Data Collection

Site(s): Bureau within the Drug Regulatory Authority or MOH which is responsible for quality control.

Data Collection

Methodology: Use interview with key informants to determine: Whether or not MOH has an active drug product testing program; Names and affiliations of the laboratories which actually perform the tests; Occasions on which testing is carried out; and the number of tests carried out in the past year, with results of tests.

Computation &

Presentation: Indicator is expressed as the total number of tests carried out. Any information which permits breaking down the total number of tests by such criteria as: reasons for test; numbers of positive and negative results; and locations of testing should also be presented.

Example: In country Q, which purchased pharmaceuticals worth US\$10,000,000 in 1993, six drugs were submitted for testing to the Regional Drug Testing Laboratory in 1993. At the time of the survey, results had been obtained for three of these items. One was found to be substandard (Paracetamol Suspension).

G.2. Use of WHO Certification Scheme (C)

- Purpose:** To assess whether the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is utilized as one mechanism to assure the quality of pharmaceutical products manufactured or purchased in a country.
- Definition:** Indicator measures the degree to which the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is used both in purchasing and in monitoring exported drugs.
- Data Collection Site(s):** MOH, Central Procurement Agency, and agency responsible for certifying Good Manufacturing Practices
- Data Collection Methodology:** Visit the relevant agencies, and review documentation of requests for certification for imported and exported drugs. Determine whether the country understands and adheres to the tenets of the WHO Certification Scheme. Make sure that country is using current version of scheme, and attempt to obtain data on the specific number of instances of each form of use which occurred in the past 12 months.
- Computation & presentation:** Score either "yes" "limited" or "no" for each of the following aspects of participation in the WHO Certification Scheme:
- | | |
|---------------------|---------------------------------|
| | Country
<u>Participation</u> |
| Member | |
| User - Procurement | |
| User - Registration | |
| Certify exports | |
- "Yes" is scored if records indicate active use of the scheme documented by requests for batch certificates (as user) and certification of manufacturer performance (as exporter). "Limited" is scored if the responsible agency states that the scheme is used, but can produce no recent documents related to its use. "No" is scored if the agency says the scheme is not used (or only has a limited idea as to the nature of the scheme).
- Example:** Country A is a member of WHO certification scheme: it uses both WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, as well as WHO Free Sale Certificate for Products of Foreign Origin as proof that they can be sold in their country of origin to register pharmaceutical products. There was no data on the number of times certifications were requested and received for imports. One export certification was issued.

G.3. Existence of a functioning system for reporting product quality complaints (C)

Purpose: To assess whether a functioning system exists which encourages health providers, pharmacies and procurement/distribution staff to make written reports on suspected product quality defects, and which processes and follows up on such reports.

Definition: A formal mechanism designed to report pharmaceutical product quality complaints must have been enacted by legislation or written regulation, or through official notification by the agency responsible. To qualify as functioning, the office responsible for administering the system must be able to produce forms for submitting complaints, and evidence that the reporting system has been used for conducting investigations about product quality.

Data Collection

Site(s): MOH, Drug Regulatory Authority

Data Collection

Methodology: Determine through a review of formal documentation on pharmaceutical product quality control how complaints about pharmaceutical quality or performance are intended to be processed. From the office or agency responsible for processing such complaints, obtain a copy of the reporting form for submitting a product complaint, and any evidence that the system has actually been in use.

Computation &

Presentation: Score the indicator according to the following categories:

- a. Formal reporting system for product quality complaints is mandated and in use.
- b. Reporting system is mandated but it is not regularly used.
- c. No formal system in place.

Example: In country Y, a formal reporting system is in place, but no evidence of its use was found in last two years.

H. Private Sector Pharmaceutical Activity

H.1. Population per private sector drug sales outlet (C)

Purpose: To estimate the number of pharmacies and other licensed drug outlets as one measure of the coverage of the private sector drug distribution system.

Definition: The indicator measures the total number of licensed private sector drug outlets, compared to the total national population.

Data Collection

Site(s): MOH, Pharmacy Board, Drug Regulatory Authority

Data Collection

Methodology: Obtain a list or a count of all licensed drug outlets. Obtain also official information about the most recent estimate of national population. If even the most recent local estimates are not current, extrapolate from the last census figure, year it was done, and population growth rate per year (or use the most recent edition of the *World Development Report*).

Computation & presentation:

The indicator is a ratio, obtained by dividing the total national population by the number of licensed private sector drug outlets.

$$\begin{array}{l} \text{Population per} \\ \text{Private Sector} \\ \text{Drug Sales Outlet} \end{array} = \frac{\text{Total National Population}}{\text{Number Licensed Private Sector Drug Outlets}}$$

Example: In country X, a total of 400 licensed private sector drug outlets are in operation. On a total population of 10,000,000 people, this yields an average of 25,000 people per licensed drug outlet.

H.2. Number of licensed or registered drug outlets per government drug inspector (C)

Purpose: To assess the number of licensed/registered drug outlets per government drug inspector, which provides rough estimates of the capacity of the government to monitor the private drug market.

Definition: Only pharmacies and other formally organized stores that are licensed to sell drugs to the public should be counted. Government Drug Inspectors are those whose primary or secondary responsibility is inspecting drug manufacturers, importers and drug warehouses and or private pharmacies and other drug outlets.

Data Collection

Site(s): MOH, Drug Regulatory Authority, Pharmacy Board

Data Collection

Methodology: Obtain the most recent information regarding the number of licensed and/or registered drug outlets. Define the categories of government staff that are officially counted as drug inspectors, and obtain an estimate of the number of such personnel that are currently employed by the government.

Computation &

Presentation: The indicator is calculated by dividing the number of licensed drug outlets by the number of actual drug inspectors. Express the results at a convenient unit of aggregation (outlets per inspector).

$$\text{Number of Licensed Drug Outlet per Drug Inspector} = \frac{\text{Number of Licensed Drug Outlets}}{\text{Number of Drug Inspectors}}$$

Example: In Country X, every drug inspector has on average 20.4 drug outlets to inspect at regular intervals.

H.3. Number of Inspections made in one year period for manufacturers, distributors and retail outlets

Purpose: To quantify the types of drug inspections taking place, which provides a rough estimate of how active is the inspection program.

Definition: This indicator measures the numbers, and types, of drug inspections which the recognized authority has carried out over a one year period.

Data Collection

Site(s): MOH, Pharmacy Board, Drug Regulatory Authority

Data Collection

Methodology: Interview key informants and review records to determine the types and numbers of drug inspections carried out over a recent 12 month period.

Computation &

Presentation: The indicator is the number of inspections carried out, broken down if possible, by type of facility inspected.

Example: In country Q, during the 12 month period from January through December 1993, Drug Regulatory Authority staff carried out 124 inspections including 10 for manufacturing plants, 8 for distributor warehouses, and 106 for retail pharmacies.

H.4. Value of total private sector pharmaceutical sales, \$US per capita (C)

Purpose: To measure the size of the total private sector pharmaceutical sales on a per capita basis.

Definition: Total private sector pharmaceutical sales estimated by the total value of retail (not counting wholesale) sales.

Data Collection

Site(s): Pharmaceutical Manufacturers Association, Retail Trade Association, Customs Agency, Ministry of Finance or Trade, international data sources such as IMS International data.

Data Collection

Methodology: After ascertaining what sources information are available study organizers must determine the most reliable method of obtaining a reasonably accurate accounting of total private sector retail pharmaceutical sales in a recent fiscal or calendar year. Obtain a reasonably accurate official estimate of the national population (as described in other indicators).

Computation &

Presentation: The indicator is calculated as the total value of private sector retail pharmaceutical sales, in US\$, divided by the national population.

$$\text{Per Capita Value of Value Private Sector Pharmaceutical Sales} = \frac{\text{Total Value of Private Sector Retail Drug Sales}}{\text{National Population}}$$

Example: In country B, the value of the private pharmaceutical sector sales was approximately \$4.20 worth of drugs per capita.

H.5. Total value of drug market, public and private sector, US\$ per capita (C)

Purpose: To assess the total amount of money spent on drugs per individual per year.

Definition: Total public sector per capita expenditures are defined as the total amount of money (in US\$ at the current rate of exchange) spent on purchasing pharmaceuticals by all public sector sources (national, regional and local budgets combined) for the most recent financial year, per individual in the population. Total private sector market are estimated by the value of total pharmaceutical retail (rather than wholesale) sales as described in the previous indicator. The periods (and exchange rates) used for private and public markets should correspond.

Data Collection

Site(s): MOH, College of Pharmacy, Ministry of Trade, pharmaceutical manufacturers, international data sources, such as IMS International reports

Data Collection

Methodology: The components of this indicator have been collected in two other indicators. Simply adjust the figures for public expenditures and private sector sales so that they would apply to the same defined period of time.

Computation &

Presentation: For the same time period, adjust the public and private sector components, and add together, then divide by the estimated national population.

$$\text{Per Capita Value of Total Drug Market} = \frac{\text{Private Sector Sales plus Public Sector Purchases}}{\text{National Population}}$$

Example: In Country B, in the previous calendar year, the total value of the drug market was US\$ 6.81 per capita (\$2.61 by the public sector and \$4.20 in the private market).

H.6. Percentage of products on National Formulary List currently manufactured in-country (C)

Purpose: To assess what percentage of the drugs on the National Formulary List (NFL) are supplied (in terms of number of products rather than dollar volume) by local manufacturers.

Definition: For the indicator to make sense, there must be a National Formulary List in existence, as well as a local drug industry. Drugs are counted as manufactured in country if they are manufactured either from raw materials or intermediate chemical constituents; drugs which are simply repackaged are not counted.

Data Collection

Site(s): MOH/local pharmaceutical manufacturer(s)

Data Collection

Methodology: Determine the number of pharmaceutical products listed on the National Formulary. For each of these products, determine if there is one or more local manufacturers currently manufacturing the product in-country, and marketing it in either generic or proprietary form. If a product is manufactured by one or more manufacturers, it is recorded as being produced in the country.

Computation &

Presentation: The indicator is recorded as a percentage, calculated by dividing the number of locally produced drugs on the National Formulary List by the total number of unique, generic products on the list, and multiplying by 100.

$$\frac{\% \text{ NFL Drug Locally Manufactured}}{100} = \frac{\text{Number Locally Produced Drugs on NFL}}{\text{Number of Drugs on NFL}} \times 100$$

Example: In country D, 42% of the drugs on the National Formulary List are locally manufactured by one of the 6 local producers.

H.7. Prices of tracer drugs in the private sector: (A) As a percentage of MOH acquisition cost; and (B) As a percentage of international indicator prices

Purpose: To measure the prices of the set of tracer drugs and compare them with MOH acquisition costs and international indicator prices.

Definition: These private sector prices are the average retail sales price for a list of 20-25 tracer drugs, based on a sample of at least 10 private outlets (over 20 if possible). MOH acquisition price is that price paid for the drug in the most recent MOH procurement, average international procurement agencies, adjusted to CIF unit price.

Data Collection

Site(s):

Data Collection

Methodology: One source for international price is the MSH International Price Guide. The retail prices of the tracer drugs should be collected directly at the retail level, either by interview or written survey. To collect prices from retail outlets begin with 10 list of tracer drugs. Visit pharmacies or other retail sites, and at each site obtain the current selling price for each of the tracer drugs is not stocked, skip that drug and go to the next. If the outlet stocks more than one brand use the least expensive product. Select the median price of each product for use in compiling this indicator.

Computation &

Presentation:

Using the median retail prices, the two parts of this indicator are calculated as follows:

The average international prices for the indicator drugs should be determined by reference to average international prices in the MSH International Drug Price Indicator Guide; the average price in this guide is FOB, and should be adjusted upward by 20% to reflect average shipping costs. For percentage of MOH acquisition costs, first divide the median retail price of each product by the MOH CIF acquisition cost and multiply by 100. Next, add up the results of this calculation for all products and divide by the total number of tracer drugs. This gives the average percentage.

Divide the retail price by the appropriate international price, taking care that units are the same (or are adjusted appropriately).

Example:

In country Q, retail prices of 25 tracer drugs were found to be on average 900% of MOH acquisition costs and 1014% of international indicator prices.

H.8. Existence of price controls for drugs

Purpose: To determine whether there exists policies and regulations controlling the prices of drugs in the private sector and whether they are enforced.

Definition: Price controls are regulations which govern markups, margins or sales prices for drugs at the manufacturer, importer, wholesale distributor and/or retail sales level.

Data Collection

Site(s): MOH, MOF, manufacturers, Importers, Wholesalers, Retail Outlets, Professional Associations, Industry Associations

Data Collection

Methodology: Interviews and document review are used to determine the presence of price controls. If feasible, price lists from wholesale and retail outlets should be used in combination with interviews, to determine whether controls are enforced.

Computation &

Presentation: This indicator is presented as yes/no concerning the existence and enforcement of price controls. If price controls are mandated, the nature of the controls should be stated.

Example: In country X, price control regulations stipulate markup of 10% by wholesalers and 15% at the retail level. Interviews with MOH officials and the Pharmaceutical Association suggest that controls are not rigorously enforced.

H.9. Availability of antibiotics without a prescription (C/R/P)

Purpose: To indicate the degree to which existing regulations on the sale of potentially harmful drugs like antibiotics, without appropriate medical authority are obeyed in practice.

Definition: This indicator measures the number and percentage of instances where an antibiotic was sold without presentation of a written prescription.

Data Collection

Site(s): Drug retail outlets near the sample of health facilities; although various types of shops and stores may be described as "drug retail outlets," in most cases the sites making up the sample will be retail pharmacies.

Data Collection

Methodology: Ascertain whether any regulations exist regarding the sale of antibiotic products without a prescription. If they do, ask which antibiotic drugs might commonly be sold over the counter without a prescription (for example, Tetracycline, Septrin). Recruit the assistance of local personnel, and attempt to purchase 10 or 20 capsules/tablets of the product in question at one randomly selected retail outlets near each of the 20 facilities in the health facilities sample (see methods described in the section on Data Collection Strategies below). Count all facilities where drugs are successfully purchased. Drugs which are purchased should be retained by the principal investigator. If facilities exist, products could be tested for quality. The investigator might also be able to determine the number of different vendor's products which are sold. Once any such applications are completed, any remaining drugs should be destroyed.

Computation &

Presentation: The indicator is recorded as a percentage, calculated as the number of successful attempts to purchase the specific drugs, divided by the total number of attempts, and multiplied by 100.

$$\begin{array}{lcl} \% \text{ Instances of Antibiotic} & = & \frac{\text{Number of Purchases}}{\text{Number of Attempts}} \times 100 \\ \text{Purchased without Prescription} & & \end{array}$$

Example: When an assessor was asked to purchase tetracycline without prescription, she was successful in 14 out of 20 attempts (70%).

V. STUDY DESIGN

This chapter describes a method of designing a pharmaceutical indicators matrix survey and then describes methods of selecting individual study units.

A survey is a statistical technique which gives a picture of a system without examining all of its units. However, in order to use this technique in a valid way, attention should be paid to two major issues while designing an indicator survey:

- how to get a representative picture of the entire system; and,
- how many health facilities to survey.

A. *Obtain a Representative Picture of the Entire System*

In any given country, important variations that exist within the pharmaceutical system should first be identified. Some aspects of the pharmaceutical system vary from district to district, or facility to facility, while others from prescriber to prescriber. These locally-variable aspects might include such things as sources for the pharmaceutical budget, drug supply systems and the likelihood of drug shortages, or prescribing practices.

Therefore it is important to ensure that facilities representing all significant variants of the pharmaceutical system are included in the sample. One way to do this is to choose four areas (districts, regions) in which to work, based on an informed division of all areas in the country into groupings based on geography, socioeconomics, population density, or key features of the health system. Some suggestions are:

- the capital city should always be included as one of the study areas,
- if the country is relatively homogeneous, simply choose three other districts at random,
- if there are contrasting conditions in different areas of the country that might be expected to influence the way pharmaceuticals are supplied and used, first organize all districts into groups based on these characteristics, then select additional study districts at random from these groups; allocate the three study districts according to the overall importance of each group in the country as a whole.

Three examples will make this more clear:

Example 1: (1) capital city, (2) highland agricultural district, (3) lowland agricultural district; (4) arid district

Example 2: (1,2) capital city and one other densely settled urban area, (3,4) two rural agricultural districts

Example 3: (1) capital city, (2,3) two rural districts with reasonably good transportation links, (4) one relatively inaccessible rural district

B. Enumerate Appropriate Number of Health Facilities

It is recommended that at least five health facilities in each of the four selected regions (or a total of twenty facilities) should be visited. The actual selection should be guided by the following factors:

- The district hospital outpatient unit would always be one of the facilities selected in each study district; select randomly if there is more than one district hospital in the district.
- For systems organized with only one basic tier of outpatient facilities below the district hospital (for example, rural health centers) select the other four as follows:
 - if geographic distances and transportation logistics allow all facilities in the district to be accessed and necessary data collected in a single day, select four of these second-level units at random from all those in the district,
 - if transportation is more difficult, select two facilities at random, and then choose two other facilities from those that are geographically close to them so that the paired facilities can be visited together.
- For systems with two tiers below hospitals (for example, polyclinics and lower level health posts staffed by paramedics), select the other four as follows:
 - choose two second-level facilities at random, and
 - choose one third-level facility for each second-level facility from among those that are administratively organized under them, or that are geographically close to them, if the administrative organization is not hierarchical.
- For systems that are organized in a different way, attempt to distribute the five facilities to be studied in each district appropriately among the possible types of facility according to their prevalence, how many patients they see, etc. Make sure that you select randomly from among the different types present in a system.

The most important concept to remember in each phase of this process is random selection - this ensures that results obtained from these health facilities are representative of the entire country.

The two other issues which need to be dealt with while designing the indicator survey relate to selection of retail pharmacies and a set of tracer drugs, as discussed below.

C. Select Retail Pharmacies

Retail pharmacies will need to be enumerated for the indicator on availability of antibiotics without prescription and for obtaining retail prices of tracer drugs. For identifying pharmacies to be surveyed for antibiotic sales, the easiest thing logistically is to select two retail pharmacies located either in the neighborhood of the health facility selected or in the same town. While taking the former approach will be simpler, it may also provide a biased picture of the retail sector pharmacies, for example such pharmacies may be more resistant to selling antibiotics without prescription, etc.

Pharmacies from among all of the pharmacies present in a town will give a more general picture of the country for this indicator. To do this, first obtain a list of all functioning pharmacies in a town from government drug inspectors or from the trade association of retail pharmacies. Assign each of these pharmacies a serial number, and then select two of these numbers randomly. (For surveying retail prices, it would be best to survey four pharmacies each region or district visited). Since pharmacies may not always be willing to share information on prices, it may be necessary to obtain assistance from local counterparts in identifying pharmacies which will provide the pricing information.

D. Select Tracer Drugs

The goal of a country's pharmaceutical system is to make available essential drugs to the public through the medium of health facilities so that major health problems can be effectively treated. In the indicator survey, assessment is made whether a competitive procurement system and the proper management of logistics involved in ensuring adequate availability of drugs at health facilities is being practiced or not. With a view to simplifying data collection without losing sight of the goal of the assessment, this is done for only twenty to twenty-five drugs, called tracer drugs. These drugs should be suggested by local implementors as drugs important to their health system, with confirmation from utilization data if feasible.

Three things should be kept in mind about these tracer drugs:

- Tracer drugs should cover all important therapeutic categories as well as important individual drugs within each category. If feasible selection should be based on drug utilization data and on data concerning value of consumption (such as ABC analysis).
- They should be available in the entire pharmaceutical system of the country which is being assessed. If this is not the case, this list should be appropriately modified in advance of the assessment to suit local realities. For example, although anti-hypertensives and anti-diabetics are important drugs, they may only be available at district hospitals in some countries. Thus the decision should be made by study implementors whether they should be included in the list of tracer drugs or not.

- A range of dosage forms - tablets/capsules, oral liquids, injections, IV solutions, topicals, etc. should be included on the list of tracer drugs.

Annex 1 provides a model list of tracer drugs by therapeutic category; this should be freely modified to reflect the situation in each country.

E. Select a List of Products Currently Available in Market

To determine whether pharmaceutical products on the market are officially registered, a sample of at least 100 products available at retail drug outlets must be enumerated. To do this:

- (1) Select a random sample of 10-20 retail drug sales outlets.
- (2) At each retail drug sales outlet select from the shelves 10 products and record the complete names and product specifications. From 100 to 200 products may be identified. If working with more than one enumerator, duplication can be avoided by assigning each enumerator a range of letters of the alphabet, with instructions to select products within the assigned range.

The drug registration data base is checked to confirm that the products on this list are registered.

A smaller sample of 20 products may be further selected, in order to determine the functionality of the computerized or manual drug registration database. The idea is to see whether or not the system can retrieve accurate information concerning the products selected. This is done in the following manner:

- (a) The list of 100-200 pharmaceutical products is arranged alphabetically and numbered sequentially.
- (b) Divide the total number of products in this list by the number 20, and round up the fraction if any, this is the sampling interval.
- (c) Select the first product randomly.
- (d) Add sampling interval to the sequential number of product previously selected, select product bearing this sequence number.
- (e) Repeat step (d) until you finish selecting the number of products.

Table 3: Selection of Smaller Sample of 20 Products from Larger List of Products in Market

NUMBER	DRUG PRODUCT	REMARKS
1	Achromycin 3% ointment (Lederle)	
2	Actidil syrup (Burroughs Wellcome)	
3	Actifed tablets (Burroughs Wellcome)	
4	Advil Ibuprofen tablets (Whitehall)	
5	Afrin Nasal Spray 0.5% (Schering)	First product selected randomly
6	Aldomet tablets (Merck Sharp & Dohme)	(Interval is 8, since total list was 160 products enumerated)
7	Atarax Syrup (Roerig)	
8	Bactrim Pediatric Suspension (Roche)	
9	Biostim tablets (Roussel)	
10	Benemid tablets (Merck Sharpe & Dohme)	
11	Bonadoxina syrup (Pfizer)	
12	Bremagan tablets (Promeco)	
13	Butazolidin capsule (Geigy)	Second product for sample
14	Capozide tablet (Squibb)	
15	Ceclor suspension (Lilly)	
16	Celestone tablet (Schering-Plough)	
17	Cervilan (Grossman)	
18	Cimogal tablet (Galen)	
19	Ciproflox capsule (Senosiain)	
20	Clarytine tablet (Schering-Plough)	
21	Cloro-Trimeton syrup (Schering-Plough)	Third product for sample
22	Cloxipen capsule (Welfer)	
23	Cholipin B tablets (Boehringer Ingelheim)	
24	Daflon-750 mg (Sanfer)	
25	Daktakort cream (Janssen)	
26	Daonil (Hoechst)	
27	Daraprim tablets (Wellcome)	
28	Deca-Durabolin injection (Organon)	
29	Demelcx tablet (Lederle)	Fourth product for sample
30	Depakene syrup (Abbott)	
31	Dermovate ointment (Glaxo)	
	etc...	

VI. DATA COLLECTION

Having designed the assessment of the pharmaceutical system, the next stage is data collection. From the description of indicators in Section III, two things related to data collection become clear. First, although data collection occurs at three levels of a national health system, that is, at Central, Regional and Peripheral levels, a good majority of the indicators are collected at central level, that is at the MOH headquarters, at headquarters of other ministries, and at the central medical stores. Regional level data collection will also be a major component of the data collection process in countries where the pharmaceutical system is decentralized to regional levels, for example at state MOH headquarters and at regional medical stores. Finally, in both centralized as well as decentralized pharmaceutical systems, data collection occurs at the peripheral level as well, that is, at a town/rural area, public sector health facilities and at town private sector retail outlets.

Second, four different methods of data collection are used: Interview, Document and Record Review, Physical Inventory and Survey. The Document and Record Review method is by far the most used method; for twelve indicators, it is either used alone or combined with other methods.

A. Interviews with Health Officials

When using interviews for collecting information on indicators, two things should be kept in mind: while selecting a person for interview, attention should be paid both to her/his position in the hierarchy as well as to the likelihood of obtaining information which is current and accurate; and secondly, to the extent possible, information collected through interviews should be validated through a review of documents and/or records.

B. Document and Record Review

This is the most commonly used method for collecting information about indicators. It also helps in validating information collected through interviews. Table 2 provides a list of persons who could be a resource on providing information on pharmaceuticals indicators.

C. Physical Inventories of Drug Stock

This method is used for the three indicators of Public Sector Pharmaceutical Logistics. Inventories should be taken at all levels of health system, that is, at:

- central medical stores,
- at least one regional store if such facilities exist, and,
- at health facility stores and stock rooms.

The purpose of taking physical inventories is to determine if the information system (manual, computerized) for inventory management works, and if the drugs are essential for proper patient care are in stock.

Before taking physical inventory, agreements should be reached with store officers on two issues. The first relates to the presence of treatment alternatives, for example, amoxycillin syrup in place of ampicillin syrup. If the alternatives are considered equivalent for the purpose of physical inventory taking, then assessors should make necessary adjustments in their calculation of stock levels and in recording presence of stockouts.

The second issue on which a-priori agreement should be reached relates to the presence of donated items in the stock. Such items in some environments are irregularly supplied and thus their presence may not be a true indicator of regular availability of that item.

For obtaining real values of current recorded stock level, either from a computerized system, ledgers, or bin cards, adjustments should be made for any recent issues which have not yet been posted. Similarly, for obtaining valid counts of current physical stock level, assessors should watch for items likely to be stored at more than one place, thus reducing the danger of producing a false undercount or stockout.

D. Surveys

Surveys are done at both public and private sectors, in government health facilities in the former and at retail pharmacies in the latter. Their methodology is described separately below:

D.1. Prescribing Practices Survey

This method is used for four of the five indicators of drug utilization and patient access. As described in the Study Design chapter, twenty health facilities spread over five regions of a country should be first randomly selected. Then at each of these facilities, prescribing data should be collected either retrospectively or prospectively.

Retrospective data are usually easier to collect than prospective data. Some possible sources of such data are chronological clinic registers, treatment records kept by individual prescribers, copies of drug prescriptions that are retained at the dispensary, or patient records kept at health facilities. In order to be useful, however, such data should have two essential elements: (1) a method of selecting a random sample of patient encounters that took place within a defined period of time; and (2) the specific names and routes of all drugs prescribed.

Prospectively collected data are usually complete, but as they are collected over a short period of time, they can suffer from biases due to seasonality, peculiarities in staffing and inconsistency in the supply cycle. For example, in certain environments, clinics for special diseases like tuberculosis and diabetes are organized in some health facilities on certain days of the week or month. If prospective data collection includes such days, some indicators will be artificially high.

D.2. Purchase Surveys at Retail Pharmacies

The technique of Simulated Purchase Survey is used for the indicator on availability of antibiotics without prescription at retail pharmacies, and it should be done in the following steps:

First select an antibiotic which is thought to be most commonly used for treatment of general bacterial infections, some examples could be co-trimoxazole, tetracycline, or ampicillin.

Next select a local person who looks employed but not affluent, for example a vehicle driver. As sex of the assessor may affect results of this survey, make sure that all of the assessors are of one sex only.

Finally, develop a simple scenario for this assessor which will be used in purchasing drug at pharmacy:

- assessor will be carrying a slip of paper on which drug's (an antibiotic) name would be written,
- assessor will tell the person attending him at a pharmacy that one of his adult relatives is suffering from a common condition such as acute diarrhea,
- assessor will then say that he/she has used the drug written on the piece of paper before with success for treating this problem, and ask attendant to sell him/her 4-6 tablets again,
- if initially refused, assessor should try one time to gently persuade the counter attendant; however if refused the second time, s/he will exit pharmacy, and finally,
- s/he will record this information on the Availability of Antibiotic Form.

Table 4: Potential Resources for Gathering Information on Indicators

Resource Person to be Interviewed	Documents and Historical Data to be Collected	Indicators
Chief Pharmacist	<p>National drug policy document</p> <p>Document on legislation and enforcing agency for components of drug control legislation</p> <p>List of drugs currently on market</p> <p>Document on generic substitution by pharmacists</p> <p>List of all licensed or registered drug outlets</p>	<p>Existence of a national drug policy</p> <p>Existence of components of comprehensive drug control legislation</p> <p>Whether all pharmaceutical products on market are currently registered</p> <p>Whether generic substitution by pharmacists is allowed</p> <p>Number of licensed or registered drug outlets per capita and per government inspector</p>
Chief of the Purchasing Unit, CMS	<p>Policy document on purchasing products not on the national EDL</p> <p>Most recent invoices on regular procurement of tracer drugs</p> <p>Data on total value of drugs purchased and value of drugs purchased through competitive tenders</p>	<p>Existence of a policy to limit public sector pharmaceutical procurement to the national public sector drug list</p> <p>Existence of a centralized system for routine procurement of public sector drugs</p> <p>Percentage of average international price paid for last regular procurement (of a set of tracer drugs)</p> <p>Percentage of MOH drugs purchased through competitive tender</p>
Head of Essential Drugs Programmes	<p>National drug formulary list</p> <p>PHC essential drugs list</p> <p>National formulary manual</p>	<p>Number of drugs on National Formulary List</p> <p>Number of drugs on PHC Essential Drugs List</p> <p>Existence of a National Formulary Manual providing basic drug information for prescribers revised within the past 5 years</p>
Head of Drug Regulatory Authority	<p>Reporting form for submitting product complaint</p>	<p>Use of WHO Certification Scheme</p> <p>Existence of a functioning system for reporting product quality complaints</p> <p>Percentage of products on national formulary list currently marketed by local manufactures</p>

Resource Person to be Interviewed	Documents and Historical Data to be Collected	Indicators
Planning Officer, Ministry of Finance	Data on total government expenditures, total expenditures on health, and expenditures on pharmaceuticals in last fiscal year Most recent census report and data on average annual population increase	Public sector expenditures on pharmaceuticals, \$US per capita Percentage of total government expenditures used for health Percentage of total government health expenditures used for pharmaceuticals
Division of Manpower Planning	List of functioning health facilities of all levels in the country	Number of public sector health facilities per capita
Superintendent, District Hospital	Data on revenues obtained from patients for drugs in last four months, and number of curative encounters in the same period	Public sector revenue generated from community participation for drugs, US\$ per curative encounter
Record keeper, Medical Store (C, P)	Data on which drugs had stockout last year, and for how long	Stockout prevalence and average stockout duration for a set of tracer drugs
Chairman, Association of Pharmaceutical Industry	Data on private sector pharmaceutical sales to non-governmental sources Names of manufactures (not repackagers) who produce any of the items on NFL	Value of total private sector pharmaceutical sales, \$US per capita Percentage of products on national formulary list currently marketed by local manufactures

VII. PLANNING FIELDWORK AND TRAINING

Although the proposed pharmaceutical system indicators in this manual are easy to collect, some preparation for the fieldwork is necessary. Such preparation will ensure that the appropriate people are involved in the survey, and that many of the operational problems which will may arise during such activity are identified beforehand (and that strategies to deal with them are in place).

The key things to concentrate on in this phase are:

- identifying important MOH officials for a defined level of participation in project activities;
- making logistical arrangements;
- identifying, recruiting, and training data collectors;
- pre-testing the survey, and making adjustments as needed; and finally
- setting two teams to divide data collection between central and regional/peripheral levels.

A. *Select Study Areas and Facilities*

Care should be taken to ensure that the methodology of data collection detailed in this manual is implemented as rigorously as possible. For example, in some environments there may be a tendency to select study areas and/or health facilities which are not representative of the region. The study director should avoid such biased selection to assure confidence in the results of the indicator survey.

The appropriate MOH officials should be encouraged to define their level of involvement before the survey and to commit to maintaining that level of involvement throughout the survey.

B. *Identify MOH Officials*

Identifying MOH officials who can regularly participate in the survey is an often neglected but a very important activity. Such involvement of a few selected officials from MOH ensures that project activities are not viewed as externally imposed. Secondly, their knowledge of the local environment often helps avoiding unforeseen operational problems, and may provide insights into the pharmaceutical system not available otherwise. Finally, as such persons are often the ultimate users of information, their involvement in project planning and execution may increase the chances that appropriate action is taken on the information collected.

C. Make Logistical Arrangements

This should be a priority area, given the poor communication and transport facilities in many environments, and chances that MOH staff may be unavailable at times when their presence might be needed, it is crucial that such arrangements be made well in advance.

Although the specific logistical arrangements needed will depend on the country where the survey is being undertaken, some arrangements will be universally needed:

Clearance Letters for the Assessment: such letters, detailing activities of the assessment and signed by appropriate officials of the MOH, should be obtained as soon as possible, and forwarded to the appropriate field officers.

Letters of Introduction: letters introducing the visiting project staff and data collectors should be developed for each project staff member.

Transportation: enough vehicles in working condition should be assigned (or otherwise obtained) by MOH for the project field activities.

D. Recruit and Train Data Collectors

Data collectors to be recruited for the assessment should be familiar with the pharmaceutical system of their country and have knowledge of basic pharmaceutical terms. Examples of such persons could be public-sector pharmacists, nurses, physicians, and drug-store keepers. When recruiting, ensure that data collectors are available for the entire length of project activities.

Although the exact number of data collectors will depend on the local situation, a working guideline is to recruit six to eight data collectors for data collection in four regions and 20 health facilities. Next the recruited data collectors should be trained for two days, using a model training course outlined in the following table.

Table 5: Model Training Course for Data Collectors

TOPIC	TRAINING AIDS	TIME
<p>1. Overview of the assessment:</p> <p>What an pharmaceutical assessment is and why MOH is interested in assessment;</p> <p>Role of data collectors;</p> <p>Work to be carried out, start and finish dates;</p> <p>Days each data collector will work, expected outputs and compensation;</p> <p>Location of sites to be visited by each data collector.</p>	Study briefing package	60 minutes
<p>2. How data are collected:</p> <p>Show physical inventory form, procurement price indicator form, availability of antibiotics indicator form, and drug utilization indicator form;</p> <p>Indicate fields for each type of data.</p>	Data collection forms	1-2 hours
<p>3. Coding prescribing encounters for Drug Util. & Pat. Ind. Form:</p> <p>Data must be organized in a standard manner;</p> <p>Form has space for date of prescription, for diagnosis (although optional), and codes for indicators;</p> <p>Form also has space for presence of national formulary indicator.</p>	Drug utilization and patient access indicators form	15 minutes
<p>4. Practice session to enter data:</p> <p>For facility inventory form, set up a dummy storage facility which is problem free, and another which has recording and storage problems and ask each data collector to fill one form for each dummy storage facility;</p> <p>Practice filling in other forms (procurement price indicator form, availability of antibiotics indicator form, physical inventory consolidation form, drug utilization and patient access indicator consolidation form).</p>	facility inventory form, procurement price indicator form, availability of antibiotics indicator form, physical inventory consolidation form, drug utilization and patient access indicator consolidation form	60 minutes
<p>5. How to draw the retrospective sample of patient encounters (if needed):</p> <p>Procedures for assembling the lists that comprise the sample frame, and listing cases;</p> <p>Linking other necessary data on drugs for the encounters if needed.</p>	A dummy patient-encounter and pharmacy register	45 minutes
<p>6. Field practice:</p> <p>Visit and collect complete set of data in one region outside of sample;</p> <p>Complete all forms.</p>	All forms	1 day
<p>7. Final discussion:</p> <p>Review experiences of field test and address concerns and questions;</p> <p>Revise data collection forms if and as needed;</p> <p>Assign data collectors to working teams;</p> <p>Finalize data collection plan and organization of work (schedules, transport, communication).</p>	Schedules, letters of introduction, per-diems	1/2 day

VIII. REPORTING FINDINGS

A. Reporting at the Administrative Level

After all this data on indicators has been collected, entered in appropriate forms, and analyzed, a meeting of key managers and policy-makers should be convened for the administrative area where the survey was conducted. Seek suggestions for invitations from the MOH officials whom you have been working with in this indicators survey. If you met someone during interviews especially interested and/or having jurisdiction over any of the areas of pharmaceutical system, invite her/him to the meeting. You should at a minimum, invite officials such as the Chief Pharmacist, Chief of Purchasing Unit, CMS, Head of Essential Drugs Programmes, Head of Drug Regulatory Authority, Planning Officer, MOH, Head, Division of Manpower Planning, Chairman, Association of Pharmaceutical Industry, Principle of Pharmacist Training School, Head of the Department of Pharmacy at a national university, NGO representatives from Missions, etc., and representative staff from the facilities surveyed. Make sure to schedule the meeting at a place and time convenient to participants, for example, avoid Monday mornings and Friday afternoons.

A memorandum detailing the purpose of the survey, methodology used, and results should be prepared and distributed to all participants in advance. Extra copies should be made available on the day of meeting. If a pharmaceutical system indicators survey has been done in countries with environments similar to the country currently being assessed, and if it is feasible, prepare a comparative matrix of results on indicators.

During the meeting, review with the group the purpose of the survey. Discuss the results from individual indicators, what the results might mean, and compare results from the current survey with results on indicators from other countries. If there were significant regional variations, discuss with participants the possible causes for the observed differences. Finally, conduct a discussion on the overall pattern of results; highlighting significant problems in the system and offering suggestions for interventions which might be considered for improving the system.

Record the issues reviewed during the discussion and decisions which are made. Discuss how the group could initiate a brainstorming session to identify approval follow-up activities in light of this information and available resources.

B. Reporting Results at the Facility

Besides reporting to the central administrative level, feedback should be given to the responsible persons at the peripheral level. Highlight any positive aspects of the assessment when comparing results with the national norms or previous performance. Ask participants for suggestions as to why there may be differences, or what makes their health facility different. If results are better than the national norms, ask for suggestions as to how the national situation could be improved. Where the results from the facility are worse, ask how the situation at the health facility could be improved. Make sure that all appropriate staff members get a copy of results and requests for feedback. Ask the staff to record any suggestions or decisions on the back of the record sheet and forward you a copy. When a follow-up visit is made, the record sheet can be used as the basis for discussion.

Annex 1: Suggested List of Tracer Drugs By Therapeutics Category

THERAPEUTICS CATEGORY	TRACER DRUGS
ANALGESICS	Acetaminophen suspension 120 mg/5ml Acetaminophen tablets 500 mg Acetyl Salicylic tablets 500mg
ANTI-CONVULSANTS	Phenobarbital tablets 100 mg
ANTI-DIARRHEAL AGENTS	Oral Rehydration Salts sachets
ANTI-INFECTIVE AGENTS	Ampicillin tablets 500 mg Ampicillin suspension 250 mg/ 5 ml Benzyl Benzoate solution 25 % Chloramphenicol eye-ointment 1 % Chloroquine phosphate tablets 250 mg Clotrimazole cream Isoniazid (INH) tablets 300 mg Mebendazole tablets 100 mg Metronidazole tablets 250 mg Procaine Penicillin injections 4 million IU Rifampicin tablets 300 mg Tetracycline capsules 500 mg Co-Trimoxazole tablets 80/400 mg
ANTI-ANEMIC PREPARATIONS	Ferrous sulphate tablets 200 mg
VACCINES	Tetanus Toxoid vaccine
ANTI-DIABETICS	Insulin Chlorpropamide 250mg tablets
CARDIOVASCULAR	Furosemide 40 mg tablets Captopril 25 mg tablets Propranolol 40 mg tablets

Annex 2: Examples of Data Collection Forms

FORM 1: Procurement Price Difference Reporting Form

FORM 2: Stockout Prevalence & Duration Reporting Form

FORM 3: Drug Utilization & Patient Access Indicators Form

FORM 4: Drug Utilization & Patient Access Indicators Consolidation Form

FORM 5: Availability of Antibiotics Indicator Form

PROCUREMENT - PRICE ANALYSIS

REGION: HEALTH FACILITY NAME:

DISTRICT:

Form 1

CODE	DESCRIPTION	STRENGTH	RTE	FORM	UNIT	CURRENT SELLING PRICE		LAST QUANTITY BOUGHT FROM CMS		FROM ANOTHER SOURCE		TOTAL QUANTITY DONATED FOR THE LAST 12 MONTHS	
						PRICE	DATE	QUANTITY	PRICE	DATE	QUANTITY	PRICE	DATE
0201	ACETYLSALICYLIC ACID	325MG	PO	TAB	TABLET								
1701	AMODIAQUINE	200MG	PO	TAB	TABLET								
0610	AMOXICILLIN	25MG/ML	PO	SUS	BOTTLE								
0611	AMPICILLIN	25MG/ML	PO	SUS	BOTTLE								
0620	CHLORAMPHENICOL	250MG	PO	TAB	TABLET								
0661	CHLOROQUINE	150MG	PO	TAB	TABLET								
0302	CHLORPHENIRAMINE	4MG	PO	TAB	TABLET								
0629	CO-TRIMOXAZOLE	480MG	OR	TAB	TABLET								
2403	DIAZEPAM	5MG	PO	TAB	TABLET								
1002	FERROUS SULFATE	60MG/IRON	PO	TAB	TABLET								
1004	FOLIC ACID + IRON	1MG/60MG	PO	TAB	TABLET								
2504	FRUSEMIDE	40MG	PO	TAB	TABLET								
0601	MEBENDAZOLE	100MG	PO	TAB	TABLET								
2609	METRONIDAZOLE	250MG	PO	TAB	TABLET								
2704	MULTIVITAMIN	BP	PO	TAB	TABLET								
1760	ORAL REHYDRATION SALT	BP	PO	POW	SACHET								
0203	PARACETAMOL	500MG	PO	TAB	TABLET								
0615	PENICILLIN PROCAINE	4MU	INJ	POW	VIAL								
0612	PENICILLIN BENZYL	5MU	INJ	POW	VIAL								
0603	PIPERAZINE CITRATE	BP	PO	FLUXID	LITRE								
1212	RESERPINE	0.25MG	PO	TAB	TABLET								
1507	TETANUS VACCINE		INJ	LQ	VIAL								
	CONDOM			DISP	EACH								
	DEPO-PROVERA		INJ	LQ	TABLET								
	LO-FEMENAL		PO	PIL	CYCLE								

NAME OF DATA COLLECTOR:

DATE:

RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT

RYAZAN SURVEY: HEALTH FACILITY - PHYSICAL INVENTORY AND STOCK RECORDS INFORMATION

RAYON:

FACILITY NAME:

PLEASE NOTE: The consumption and out-of-stock data should be reported for 1993
If this is not possible, state period for which data is entered: _____

[illegible]

DATA COLLECTOR:

DATE:

PATIENT CARE FORM

Location: _____

Date: _____

Investigator: _____

Seq. #	Patient Identifier (if needed)	Consulting Time (mins)	Dispensing Time (secs)	# Drugs Prescribed	# Drugs Dispensed	# Adequately Labeled	Knows Dosage (0/1)
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							
Count							
Total							
Average							
Percentage							
				% of Prescribed	% of Dispensed	% of Cases Asked	

DRUG USE INDICATORS CONSOLIDATION FORM

Location: _____

Date: _____

[illegible]

GHANA MINISTRY OF HEALTH
RATIONAL PHARMACEUTICAL MANAGEMENT PROJECT
GHANA COUNTRY ASSESSMENT

AVAILABILITY OF ANTIBIOTICS WITHOUT PRESCRIPTION

DRUG OUTLET: _____

DATE : _____

SCRIPT:

The enumerator must first identify the private drug outlet that is closest to the health facility. But, the enumerator cannot visit this outlet. He must find another person who is unrelated to the health facility. After selecting this person, you must provide him with the following script to follow.

1. His objective is to try to buy an antibiotic drug without showing a medical prescription.
2. Go to the identified private drug outlet.
3. Ask the attendant to sell _____ capsule/tablets of _____.
4. If the attendant asks for the prescription, tell him "I don't have one".

If the attendant asks for whom you are buying the antibiotic, tell him "It is for my brother who has diarrhoea".

If the attendant asks his age, the answer is "24 years old".

If the attendant asks why you want the antibiotic, say "I took it sometime ago and it is good for diarrhoea".

If the attendant sells the antibiotic, take it and leave the drug outlet.

If the attendant says that he cannot sell it without a prescription, try to convince him one more time. If he again refuses to sell the antibiotic, leave the drug outlet.

5. Give the purchased antibiotic to the enumerator.

Drug outlet: _____

The drug outlet ☐ sold the antibiotic
☐ did not sell the antibiotic

Information on the purchased product:

Generic Name: _____ Brand Name: _____

Price/Unit : _____/_____

Enumerator: _____ Signature: _____

Annex 3: References

1. World Health Organization/Action Program for Essential Drugs. **Report for the Biennium 1990-1991**. Geneva: February 1992.
2. Management Sciences for Health, Ministry of Health, and Yayasan Indonesia Sejahtera. **Child Survival Pharmaceuticals in Indonesia: Opportunities for Therapeutics & Economic Efficiencies in Pharmaceutical Supply and Use**. Jakarta: December 1987.
3. WHO Drug Action Programme. **WHO/UNICEF Study on the Stability of Drugs During International Transport**. WHO/DAP/91.10. Geneva: 1991.
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5. WHO. **Guidelines for National Drug Policies**. Geneva:
6. WHO/Action Programme on Essential Drugs. **How to Investigate Drug Use in Health Facilities**. WHO. Geneva: 1993.
7. World Health Organization. **World Drug Situation**. Geneva: 1988.
8. Sallet, J. and Frye, J. **International Drug Price Indicator Guide, 1992-93**. Management Sciences for Health, 1993.

Annex 4: PHARMACEUTICAL INDICATORS - COMPARATIVE RESULTS OF PILOT TESTS

Field Tests Conducted Under LAC/HNS Contract and Rational Pharmaceutical Management Project

	GHANA	GUATEMALA	ECUADOR	JAMAICA
POLICY, LEGISLATION AND REGULATION	June 1993	Sept 1992	Oct 1992	Nov-Mar 1993
1. Existence of National Drug Policy approved by Government	No	Yes	Yes	Yes
2. Existence of drug legislation with specific components	Yes	Yes	Yes	Yes
3. Proportion of sampled products registered or licensed	N/A	92.6%	100.0%	79.0%
4. Type of registration system	Manual	Computerized	Mixed	Manual
5. Law regarding generic substitution	No law	No law	No law	No law *

FORMULARY/ESSENTIAL DRUGS LISTS & DRUG INFORMATION

1. # drugs on national formulary list	222	428	438	1010
2. # drugs on sub-set EDL	No list	50	237	VEN lists *
3. Existence of National Formulary and/or EDL Manual with basic therapeutic information revised within last 5 years	No	Yes	Yes	Yes
4. % of visited public facilities with most current formulary or ED Manual at public sector facilities	45%	30%	25%	100%

PUBLIC SECTOR BUDGET AND FINANCE

1. Public sector pharmaceutical expenditure per capita +	\$0.46 *	\$3.93	\$0.09	\$1.98
2. Public sector revenue from pharmaceutical cost recovery per curative encounter	N/A	N/A	N/A	N/A
3. % of total government expenditures used for health budget +	14.1%	15.0%	7.5%	3.4%
4. % of total government health expenditures + used for pharmaceuticals	No budget; all cost sharing	26.0%	1.3%	8.0%

PUBLIC SECTOR PROCUREMENT

1. Existence of policy to limit public sector procurement to items on National Formulary or EDL	Yes	Yes	Yes	Yes
2. Coverage by centralized system for routine procurement of public sector drugs +	Yes % not available	27.0%	< 50.0%	80.0%
3. % of average international price paid for last regular procurement of indicator drugs	79%	164-371 %	161%	145%
4. % of MOH drugs purchased through competitive methods +	87% *	10%	45%	95%

Annex 4 (cont):

PUBLIC SECTOR LOGISTICS		GHANA	GUATEMALA	ECUADOR	JAMAICA
		June 1993	Sept 1992	Oct 1992	Nov-Mar 1993
1. % variation between inventory records and physical stock (CMS)	Tally	0.0%	not calculated		48.4%
	Ledger	14.6%	5.0%	2.6%	
2. Availability in warehouses and health facilities of set of tracer drugs	CMS	100.0%	93.0%	93.3%	100.0%
	RMS	87.0%		86.7%	
	H.C.	60.0%	60.0%	38.0%	
3. % of time out of stock for tracer drugs (CMS)		8.0%	32.0%	79.0%	27.0%

DRUG UTILIZATION
INRUD Averages

1. Population per public health facility +	34,308	8,529	6,310	5,800	
2. Average number of drugs prescribed per curative encounter	4.3	1.4	1.3	2.4	2.1
3. % of drugs prescribed by generic names	59.4%	72.0%	37.0%	39.5%	66.7%
4. % of patients receiving injections	55.7%	13.0%	19.0%	3.7%	24.7%
5. % of patients receiving antibiotics	46.6%	27.0%	27.0%	30.0%	43.2%
6. % of drugs prescribed which are actually dispensed	86.0%				76.5%
7. Average duration of dispensing interaction (seconds)	125				58.8
8. Percentage of drugs adequately labelled	12.0%				
9. Patient knowledge of correct use of dispensed drugs	76.0%				64%

PRODUCT QUALITY ASSURANCE

1. Use of WHO Certification Scheme	Limited	Limited	Limited	Limited
2. Existence of functioning system of reporting product quality complaints	No	No	No	No

PRIVATE SECTOR PHARMACEUTICAL ACTIVITY

1. Population per licensed private sector drug outlet +	3,438	4,805	3,419	9,700
2. Drug outlets per government drug inspector	262	947	13 *	62.5
3. Value of total private sector pharmaceutical sales per capita +	N/A	\$10.98	\$7.87	\$10.28
4. Total value of drug market, public and private sectors per capita +	N/A	\$14.91	\$7.96	\$12.27
5. % of products on National Formulary which are manufactured or co-manufactured locally +	70%	71%	50%	15-20%
6. Percentage of instances where an antibiotic was available from a licensed outlet without a prescription	85%	100%	100%	

Notes (see indicator description marked + and data marked *)

- Indicators marked by "+" yield estimated data of varying reliability, rather than exact data.
 - Ghana drug expenditures reflect CMS purchases only; there were also substantial direct purchases by regional stores and health facilities.
 - Ghana competitive procurement percentage also reflects only CMS purchases.
 - Jamaica has recently passed a law which regulates generic substitution.
 - Jamaica health facilities have individual VEN lists which are functionally equivalent to sub-set essential drug lists.
 - In Ecuador, there are 240 health inspectors whose duties include pharmacy inspections; most have no specific training in this field.
- Grey shading indicates information was not collected in the survey.